Petition Control Branch
Procter & Gamble Co.
25 February 1999

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FOOD ADDITIVE PETITION
ENVIRONMENTAL ASSESSMENT
FOR OLESTRA

Prepared by

The Procter & Gamble Company
Cincinnati, Ohio

25 February 1999

CONTENTS

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SUMMARY: OLESTRA ENVIRONMENTAL ASSESSMENT

The Procter & Gamble Company is filing a new olestra petition and enclosing an environmental assessment, prepared in accordance with FDA's "Recommendations for Preparing an Environmental Assessment (EA) for Olestra". Approval is being requested to amend the olestra food additive regulation (CRF 172.867) to permit the use of olestra in pre-packaged unpopped popcorn kernels that are ready-to-**heat**. The use of olestra as a food additive in popcorn production will have no significant adverse consequences on either natural environments or engineered treatment systems because (1) the total estimated consumer consumption of olestra used to determine environmental exposure in the previously accepted EA for savory snacks included olestra from all pre-packaged popcorn sources and, therefore, already included an assessment of the environmental impact of consumption of ready-to-heat popcorn, and (2) the estimated environmental release of olestra from a representative popcorn plant is less than that from a typical potato chip plant.

As with the previous EA, olestra will be non-toxic to aquatic and benthic organisms. It will not bioaccumulate. In digested sludge and sludge-amended soil, olestra will comprise a small fraction of the total fats, oils and greases (FOG) present, with no toxic effects on soil microflora, invertebrates and plants. The ingredient will have no adverse consequences on either municipal or home wastewater treatment processes. Olestra will not be mobile in soil and will biodegrade in soil environments at rates which will prevent significant accumulations. This overall conclusion of environmental safety is established for the use of the proposed range of olestra compositions.

OLESTRA ENVIRONMENTAL ASSESSMENT

1. Date: 25 February 1999

2. Name of petitioner: The Procter & Gamble Company

3. Address: Winton Hill Technical Center
6071 Center Hill Road
Cincinnati, OH 45224

4. Description of proposed action:

a) Requested approval

The Procter & Gamble Company proposes to amend the olestra food additive regulation to permit its use in pre-packaged unpopped popcorn kernels that are ready-to-**heat**. Manufacturing will be in accordance with good manufacturing practices. As provided in 21 CRF 172.867, olestra is permitted for use as a replacement for triglyceride in savory snacks. This new petition, including this EA, contains data that support its use in pre-packaged ready-to-heat popcorn. Accordingly, Procter & Gamble Company proposes that 21 CRF 172.867 be amended to designate olestra as a replacement for triglyceride (up to 100%) in pre-packaged unpopped ready-to-heat popcorn kernels.

The previously accepted EA (Attachment A) for savory snacks included both ready-to-**eat** and ready-to-heat popcorn as sources of olestra released to the environment since all pre-packaged sources of popcorn (both ready-to-**eat** and ready-to-**heat**) were included in the estimated consumer intake of popcorn. Therefore, we have determined whether there is anything unique about ready-to heat popcorn production or consumer consumption and included it in this EA. This assessment shows that the use of olestra in pre-packaged ready-to-**heat** popcorn is expected to have no adverse environmental impact.

b) Need for action

Olestra is intended for use as a calorie-free replacement for fats and oils. Because of its inherent safety profile, and excellent cooking properties, olestra provides an ideal replacement for traditional fat in preparing salty snacks, including pre-packaged ready-to-heat popcorn.

c) Location of use

Olestra will be sold to manufacturers of pre-packaged ready-to-heat popcorn products for incorporation into these products as a triglyceride replacer. Ultimately, olestra-containing products will be sold to and eaten by consumers as a component of the human diet in patterns corresponding to national population density.

We have evaluated the environmental release profile of pre-packaged ready-to-heat popcorn plants versus the Procter & Gamble Jackson food plant, a snack production location included in the previously accepted EA (Attachment A). We have concluded that the Jackson plant continues to represent a reasonable worst-case scenario for the manufacture of olestra snacks, including pre-packaged ready-to-heat popcorn. This is because, as described below in detail, the manufacture of popcorn generates less environmental waste.

The Jackson plant is a large plant in a relatively small community. A listing of pre-packaged, ready-to-heat popcorn plants whose combined production represents over 70% of the market volume of this product is provided in Attachment B. All of these plants are smaller than the Jackson plant (fewer employees) and most of them are located in metropolitan areas of the same size or smaller than Jackson. The remaining 30% of the market is divided amongst snack manufacturers who do not separately list where they produce pre-packaged ready-to-heat popcorn; however, we are aware of no popcorn plants larger than the Jackson plant. Therefore, with respect to location, the Jackson plant remains a reasonable worst-case model for the assessment of the environmental impact of olestra.

In addition to the location, the Jackson plant provides a reasonable worst-case example for olestra's environmental safety since the processes used for producing olestra chips at the Jackson plant generate more waste than those which will be used for producing pre-packaged, ready-to-heat popcorn (Table 4-1). The maximum amount of oil used in the production of snacks at the Jackson plant, 45 million lbs/yr, was derived by assuming that all of the triglyceride used in the production of snack foods is converted to olestra. Similarly, we assumed that the 16 million lbs/yr of triglyceride used in pre-packaged ready-to-heat popcorn produced at a large, representative popcorn plant is converted to olestra. This annual volume of usage at a large popcorn plant is about one-third that used at the Jackson plant. From the maximum yearly volume of olestra that will be used at these plants in the production of snacks or popcorn, the annual amounts of various environmental releases were calculated as described below and as shown in Table 4-1.

TABLE 4-1
COMPARISON OF OLESTRA WASTE SOURCES FROM SNACK AND POPCORN PLANTS [1]

	Maximum Oil Use (million lbs/yr)	Air Emission (thousand lbs/yr)	Waste Olestra (thousand lbs/yr)	Waste Product (thousand lbs/yr)	Discharge to POTW (thousand lbs/yr)
Snacks [2]	45	108	2,250	225	63
		(0.24%)	(5%)	(0.5%)	(0.14%)
Popcorn [3]	16	0	54	80-304	22
		(0%)	(0.34%)	(0.5-1.9%)	(0.14%)

[1] see Section 6 of previously accepted EA (Attachment A) for additional details on snacks; information on popcorn is from a pre-packaged ready-to-heat popcorn producer

[2] Jackson plant

[3] represents one of the highest volume pre-packaged ready-to-heat popcorn plants in the U.S.

The frying process used to make snacks results in air emissions of olestra particulate. At the Jackson plant, air emissions are expected to be the same size and quantity as that resulting from triglyceride frying oils. For the previously accepted EA (Attachment A), it was assumed that as much as 0.24% of the 45 million lbs/yr, or 108,000 lbs/yr, of olestra would be emitted in the air. In contrast, since there is no frying step in the production of pre-packaged ready-to-heat popcorn (olestra is added directly to the popcorn bag), there will be no air emissions.

Assuming worst-case Jackson processes, about 5% of the olestra used for frying ends up as waste oil. This waste oil, as much as 2.25 million lbs/yr, is either converted to fatty acids for use in animal feed, incinerated as a fuel source, or landfilled. In the case of popcorn plants, waste oil is estimated to be <0.5%, or 54,000 lbs/yr, since oil is delivered directly into the popcorn bags through a much simpler delivery system (e.g., no fryers/heat exchangers and fewer valves, pumps, conveyances, etc.) and shorter lines. As well, the simplicity of the popcorn system presents fewer places for leaks to occur, and wash out of the lines during routine cleaning results in less waste since there are fewer components that become coated with the oil. As with olestra savory snacks, liquid waste materials generated in the production of pre-packaged, ready-to-heat popcorn containing olestra will be recycled, converted to materials usable for animal feed, or discharged to the sewer.

During the production of snacks at the Jackson plant, about 0.5% of the 45 million lbs/yr (225,000 lbs/yr) of oil is disposed of in waste product that does not meet quality control standards for product release (e.g., out of specification on one or more parameters). Waste oil in pre-packaged ready-to-heat popcorn will be similar to the amount of oil in other snack products with ranges from 0.5-1.9% (80,000-304,000 lbs/yr). The high end of this range represents a upwardly conservative estimate from a representative plant since this value was derived during a time when plant start up occurred and more than normal waste was generated. It is expected that during

normal, ongoing operations, the waste oil in product will be closer to the 0.5% seen in a snack plant. This product waste, whether snacks or popcorn, will be landfilled. Since olestra is not mobile in soil and is not volatile, it will be effectively entombed and not be released to the environment.

The discharge of waste oil to POTW from popcorn production will be similar to or less than that for other snack production. For example, at one of the largest pre-packaged ready-to-heat popcorn production facilities, essentially no waste oil is discharged to the POTW since all triglyceride liquid wastes are present as solids at operating temperatures and are collected for recycling, rendering, or landfilling. For purposes of this assessment, we have conservatively assumed the same percentage of olestra discharge at a typical popcorn plant as observed at the Jackson plant. Based upon this, as much as 22,000 lbs/yr of olestra will be discharged to the POTW from a popcorn plant versus as much as 63,000 lbs/yr from the Jackson plant. Therefore, the Jackson plant continues to serve as a reasonable worst-case model and is used in Section 6 of the previously accepted EA (Attachment A) to assess the environmental impact of production of olestra snacks.

d) Location of disposal

Following consumption, disposal is expected to occur nationwide with excreted olestra entering publicly owned treatment works (POTWs) or septic tanks.
The most significant release of olestra to the environment will occur via excretion of human wastes following consumption of the olestra-containing products. It is important to note that the environmental impact of human wastes provided in the previously accepted EA (Attachment A) for the use of olestra in savory snacks already included wastes from the consumption of ready-to-heat popcorn. This is because previous FDA assessments included the contribution of olestra from all popcorn sources, whether pre-packaged ready-to-eat or ready-to-heat, in the overall olestra intake estimates. The amount by weight of olestra in popcorn is similar to that

in other savory snacks (~30%). Therefore, the previously accepted EA (Attachement A) supports this new food application of olestra with respect to human waste. Disposal will also include consumer wastes such as discarded food products containing olestra and the residual olestra left in the package after preparation of the popcorn. Waste popped popcorn is expected to contribute minimally to the waste solids generated by consumers eating other savory snacks since it contains the same percentage of olestra by weight and is only 7% of the savory snack market volume (pounds of product) (Snack Food & Wholesale Bakery. June 1998. pp. SI-38-39). This waste will be landfilled or incinerated with regular household solid refuse as with savory snacks. The amount of olestra remaining in the popcorn bag after preparation is expected to be about 20% of the initial weight of olestra. A typical amount of olestra per popcorn bag is about 30-40 g. Therefore, contribution of this remaining olestra, <6-8 g/bag, will be landfilled or incinerated when consumers dispose of the bags with household trash. The combined amount of consumer wastes - olestra from uneaten popped popcorn and residual olestra in the bags - is expected to be similar to or less than the total amount of olestra from savory snacks which are not consumed and their bags which are disposed of as household waste. As noted previously, landfilled olestra waste is considered not to be a release to the environment since it is immobile in soil.

5. Identification of chemical substances that are the subject of the proposed action:

Nomenclature: Olestra

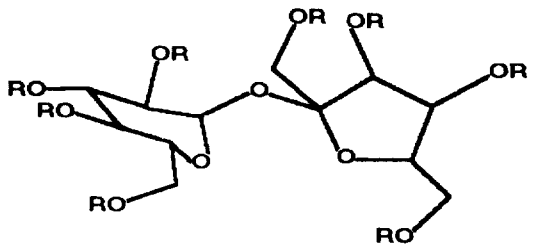
Olestra is a mixture of the hexa- to octaesters of sucrose with the naturally occurring fatty acids obtained from edible fats and oils.

CAS number: 121854-29-3

Molecular weight: 2400 daltons (average)

Molecular formula: Unspecified

Structural Formula: The representative structural formula for typical mixtures of olestra is:



Where R is a fatty acid substituted in six, seven, or eight of the available positions and H- in the rest.

Physical Description: Olestra is a fat-like material that resembles ordinary triglycerides in its physical properties. These properties may be varied through the selection of the fatty acids that are used for esterification. Olestra can range from a near liquid to a solid at environmental temperatures (20°C) depending on the degree of unsaturation of the fatty acid moieties (olestra composition specifications provided on next page).

For environmental fate and effects testing, the liquid olestra samples were approximately 80% (± 10) unsaturated while the solid olestra samples were approximately 65% (± 10) saturated. In comparison, the olestra composition specifications (next page) define an unsaturation upper limit of 83% and a saturation upper limit of 75%. The rationale for how the data obtained provide reasonable assurance that the range of olestras commercially available are environmentally safe is discussed in Section 6 of the previously accepted EA (Attachment A).

The solubility of olestra in various solvents is similar to that of triglycerides. Olestra is insoluble in water and soluble in organic solvents such as hexane, tetrahydrofuran, ethylene dibromide, ether, chloroform and oils. Olestra can be converted to fatty acids and sucrose by acid hydrolysis. By a similar process, triglycerides can be hydrolyzed to fatty acids.

Additives: Vitamin E as d-α-tocopheryl acetate. Conventional fats and oils post-processing additives may also be used.

Olestra Specifications: Olestra will meet the Food Chemicals Codex specifications and analytical methodologies.

Changes with Heating: Olestra will undergo heating during snack production (i.e., frying). Detailed analytical characterization of olestra and triglyceride heated under conditions more severe than those used in production of savory snacks shows that the same chemical changes occur in both materials. No new components were formed in heated olestra which were not also present in heated triglycerides (as the glyceride analog). In addition, it was shown that unheated olestra, used in the environmental studies, contained nearly all of the components present in heated olestra.

The primary changes which occur upon heating olestra and triglycerides are oxidation of fatty acid side chains, hydrolysis of the ester bonds, and formation of polymer, most (>80%) of which is dimer. The viscosity of both olestra and triglycerides increases slightly after heating due to the presence of the polymer and as result of increased hydrogen bonding of the oxidized fatty acid side chains (see Procter & Gamble Heated Olestra Submission to the FDA; 10/29/90). The changes that occur with heating olestra should not significantly alter the treatability, fate including biodegradation rate, or toxicity potential of olestra. The conclusions of the environmental testing program therefore apply to olestra which has been heated during snack production.

6. Introduction of substances into the environment

a) Introduction of substances in to the environment as a result of manufacture:
We have evaluated the manufacture of olestra and determined that there are no extraordinary circumstances with its manufacture. Additionally, the olestra manufacturing plant operates in compliance with all Federal, State, and local environmental laws and requirements (40CFR1508.27 (b)(10)) as shown in Section 6 of the previously accepted EA (Attachment A).

b) Introduction of substances in to the environment as a result of use:
Introduction of a macronutrient replacer such as olestra into the environment as a result of its use will be minimal since macronutrient substitutes are intended to be incorporated into food and to remain with food until ingestion by consumers. Environmental waste sources from a representative popcorn production plant will be less than that from a typical snack production plant. See Section 4.c. of this EA for further details on estimated quantities of environmental releases and disposition of product waste from ready-to-heat popcorn, and Section 6 of the previously accepted EA (Attachment A) for details on snacks.

c) Introduction of substances in to the environment as a result of disposal:
The most significant release of olestra to the environment will occur via excretion of human wastes following consumption of the olestra-containing products. Olestra from human wastes will enter POTWs or septic tanks. The environmental impact of human waste is already incorporated into the previously submitted EA since consumer intake included all sources of pre-packaged ready-to-eat and ready-to-heat popcorn. See Section 4.d. of this EA and Section 6 of the previously accepted EA (Attachment A) for further details.

The calculations for the initial concentration of olestra in sludge-amended soil have

been revised using the most recent EPA regulations for the use and disposal of sludge (Federal Register, 1993). In these recent regulations, an annual application rate of 1.0 kg sludge/m^2 is used instead of 3.7 kg sludge/m^2. Therefore, the maximum soil concentration of olestra following application of sludge from a POTW receiving consumer waste is estimated to be 179 mg/kg. The contribution to the concentration of olestra in sludge-amended soil from the Jackson plant is estimated to be 87 mg/kg. The total concentration of olestra in soil amended with sludge from the Jackson POTW receiving waste from both consumer consumption and the production plant is 266 mg/kg (Attachment C, Exhibit 10; revised from previously accepted EA in Attachment A).

Similarly, the calculation of olestra accumulation in sludge-amended soil accounting for biodegradation has also been revised. Olestra soil accumulation estimates can be based on the 10 day and 88 day half-lives and loading rate of 179 mg/kg. As in the previously accepted EA, over the representative extremes of formulations, the difference in the degradation rates does not significantly affect the steady-state olestra soil levels. It is estimated that only 6% (0-10 mg/kg) of the olestra would remain in the soil between annual sludge applications (Attachment D, Exhibit 15; revised from previously accepted EA in Attachment A).

There will be minimal product waste, including uneaten product and popcorn bags containing residual olestra which remains after popping, discarded in the household trash. These sources of waste are expected to be similar to or less than that of currently marketed olestra savory snacks since the olestra content by weight of popcorn and snacks is similar and since ready-to-heat popcorn contributes only 7% of the market volume (pounds) of all snacks. Solid wastes will be landfilled or incinerated. Landfilled waste is considered not to be an environmental release since it is effectively entombed. See Section 4.d. and Section 6 of the previously accepted EA (Attachment A) for further details.

7. Fate of substances released into the environment:

The results of the mobility and terrestrial biodegradation studies demonstrate that olestra will not be mobile or persistent in terrestrial settings. Biodegradation studies show that across the range of liquid and solid forms, the material will biodegrade in waste treatment and terrestrial matrices. There is also good indirect evidence (i.e., CO_2 screening test and activated sludge study) that olestra will degrade in surface waters. Fish studies showed no bioaccumulation of olestra. Furthermore, since olestra shows little mobility in soil it has limited potential to contaminate ground water resources beneath sludge-amended soils or septic tank tile fields. Refer to previously accepted EA (Attachment A) for details.

8. Environmental effects of released substances:

Olestra is nontoxic at levels far in excess of those predicted for aquatic environments. Terrestrial species including soil microbes, earthworms and crop plants were not adversely affected by exposure to olestra at concentrations greater than the maximum expected in sludge-amended soils. Moreover, biodegradation studies demonstrate that olestra will not persist in sludge-amended soils. From the standpoint of municipal treatment, levels up to 50-times higher than those expected in sewage produced no detrimental effects on primary or secondary wastewater treatment. Effects on anaerobic digestion were tested up to 10-times the maximum levels expected in digested POTW sludge, with minimal effect. Olestra accumulation in septic tanks is not expected to require more frequent pumping because the accumulation in the tank will be insignificant and because olestra does not have adverse effects on settling or anaerobic digestion. Olestra is unlikely to increase tile field failures through increased organic loading because the amount of olestra in the effluent will be small relative to other organics, and olestra does not interfere with the metabolic activity of soil microbial communities. Refer to previously accepted EA (Attachment A) for details.

9. Use of resources and energy:

Refer to Attachment A: previously accepted EA submitted to FAP 7A3997 on 5 April 1995.

10. Mitigation measures:

Refer to Attachment A: previously accepted EA submitted to FAP 7A3997 on 5 April 1995.

11. Alternatives to the proposed action:

Refer to AttachmentA: previously accepted EA submitted to FAP 7A3997 on 5 April 1995.

12. List of preparers:

Refer to Attachment A: previously accepted EA submitted to FAP 7A3997 on 5 April 1995. Additionally, the following changes are made:

Gregory S. Allgood. Associate Director, Food and Beverage Regulatory & Clinical Development, with Ph.D. in Toxicology (North Carolina State University, 1986) and M.S.P.H. in Environmental Biology (University of North Carolina - Chapel Hill, 1983), and 13 years experience in food, drug, and cosmetic product development.

Susan M. White, Senior Scientist, Food and Beverage Regulatory & Clinical Development, with Ph.D. in Toxicology (Purdue University, 1986), and 9 years experience in food, drug, and cosmetic product development.

13. Certification:

The undersigned official certifies that the information presented is true, accurate and complete to the best of Procter & Gamble's knowledge.

Name: G.S. Allgood Title: Associate Director
Regulatory & Clinical Development

Date: 2/25/99 Signature: [signature]

14. References:

Refer to Attachment A: previously accepted EA submitted to FAP 7A3997 on 5 April 1995, and the following new publications:

1. Allgood, G.S., D.C. McAvoy and D.M. Woltering. 1997. Environmental assessment of a new food ingredient, the fat replacer olestra. Environ. Toxicol. Chem., 16(3): 586-600.
2. Federal Register Vol. 58, No. 32, p. 9296, February 19, 1993.
3. Lee, D.M. and R.M. Ventullo. 1996. Degradation of olestra, a non caloric fat replacer, by microorganisms isolated from activated sludge and other environments. Biodegradation, 7: 257-265.
4. Logan, T.J., B.J. Harrison, D.C. McAvoy and J.A. Greff. 1996. Effects of olestra in sewage sludge on soil physical properties. J. Environ. Quality, 25: 153-161.
5. McAvoy, D.C., J.A. Greff, D.R. Webb and G.S. Allgood. 1998. Effects of olestra on organic and solids removal in septic tanks. GWMR, Fall:1, pp. 31-138.
6. McAvoy, D.C., R. Shimp, E. Namkung and V.C. Hand. 1995. Fate and effects of olestra, a fat substitute, during conventional wastewater treatment. Water Envrion. Res., 68(2): 169-177.
7. Snack Food & Wholesale Bakery. June 1998. pp. SI-38-39.

15. Attachments:

The following materials are attached to this assessment:

A. Attachment A: Olestra Environmental Assessment submitted to FAP 7A3997 on 5 April 1995.*

B. Attachment B: Appendix 1 - Revised: Distribution of snack, cracker, and pre-packaged ready-to-heat popcorn plants by size of plant versus size of metropolitan area

C. Attachment C: Exhibit 10 - Revised: Initial concentration of olestra in sludge-amended soil

D. Attachment D: Exhibit 15 - Revised: Calculation of olestra accumulation in sludge-amended soil accounting for biodegradation

* Copies of the reports submitted with the EA can be provided on request.

Petition Control Branch
Procter & Gamble Co.
25 February 1999

ATTACHMENT A

OLESTRA ENVIRONMENTAL ASSESSMENT

FAP 7A3997

Submitted 5 April 1995

FOOD ADDITIVE PETITION ENVIRONMENTAL ASSESSMENT FOR OLESTRA

Prepared by

The Procter & Gamble Company
Cincinnati, Ohio

With assistance from

ENVIRON Corporation
Arlington, Virginia

April 5, 1995

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REFERENCES

STUDY FINAL REPORTS

OVERALL SUMMARY OF OLESTRA ENVIRONMENTAL ASSESSMENT

Based on the information presented in Sections 4 through 8, the manufacture and use of olestra as a food additive in savory snack production will have no significant adverse consequences on either natural environments or engineered treatment systems. Olestra will be non-toxic to aquatic and benthic organisms and sediments and it will not bioaccumulate. In digested sludge and sludge-amended soil, olestra will comprise a small fraction of the total fats, oils and greases (FOG) present, with no toxic effects on soil microflora, invertebrates and plants. The material will have no adverse consequences on either municipal or home wastewater treatment processes. Olestra will not be mobile in soil and will biodegrade in soil environments at rates which will prevent accumulations. This overall conclusion of environmental safety is established for the use of the proposed range of olestra compositions.

1. Date: April 5, 1995

2. Name of petitioner: The Procter & Gamble Company

3. Address: Winton Hill Technical Center
   6071 Center Hill Road
   Cincinnati, OH 45224

4. Description of proposed action:

   Approval is being requested for a food additive petition for olestra.

   The Procter & Gamble Company submitted an initial environmental assessment (EA) for olestra on 4/1/87 as part of FAP 7A 3997. This assessment was revised on March 18, 1991 to incorporate the results and conclusions of subsequent exposure, fate and effects testing. The EA was revised again on 4/11/94 to respond to comments in FDA's letter of May 28, 1993 and March 22, 1994. This current version of the EA responds to verbal comments and requests made in a meeting on February 8, 1995 and in a discussion held on March 24, 1995. The comments made in the meeting on February 8, 1995 were subsequently submitted to us in writing on March 6, 1995.

   Olestra will be produced at an existing manufacturing facility owned and operated by The Procter & Gamble Company at 5201 Spring Grove Avenue, Cincinnati, Ohio, 45214 ("Ivory dale"). Snack foods production using olestra as a triglyceride substitute will take place at The Procter & Gamble Company at 1306 Highway 70 Bypass, Jackson, Tennessee, 38301 ("Jackson") as well as at a number of as yet unidentified savory snack production plants around the country. The environmental setting of Ivorydale is typical of the industrialized section of a large urban area while that of Jackson is typical of the industrialized section of a rural area. For the purposes of this assessment, quantities of waste material generated assume that all olestra is produced at the Ivorydale location, that the necessary methyl esters

are purchased from commercially available sources, and that all snack food production at the Jackson plant is converted to olestra. The estimated quantity of olestra that will enter the environment from consumption of savory snacks is about 502 million pounds per year, based on the intake estimates submitted May 26, 1993, adjusted upward by 10% as per the December 24, 1990 letter from John Gordon, FDA, to P&G, providing an intake estimate of 3.1 grams olestra/person/day times 80.6% of the population (Harrass et al. 1990). These calculations are detailed in Exhibit 1. Additional substances will enter the environment as a result of the manufacture of the olestra and of olestra-containing snacks. These emissions are listed in Tables 6-1 (page 7) and 6-3 (page 10) and are quantified in Tables 6-4 (page 11) and 6-5 (page 17). A listing of snack and cracker plants is provided in Appendix 1 (page 79). There are about 220 snack production facilities and about 120 biscuit and cracker facilities in the U.S.

Waste materials generated in the manufacture of olestra and the production of snack foods will be discharged or disposed of depending upon their characteristics: 1) the minimal amounts of gases and vapors that are generated will be controlled but with some release to the atmosphere; 2) liquid wastes will be recycled, converted to materials usable for animal feed, or discharged to the sewer; 3) solid wastes from the manufacture of olestra will be landfilled. Off-quality chips and snacks will be landfilled. No hazardous wastes as defined by the Resource Conservation and Recovery Act (RCRA) will be generated in the manufacture of olestra or the production of snack foods. The dilute methanol wastewater is expected to be less than 24% alcohol and thus a non-hazardous waste under the RCRA regulations (40 CFR § 261.21 (a) (1)). See Section 6 for details on waste materials expected.

The county in which the Ivorydale manufacturing plant is located (Hamilton County) is classified as an attainment area under the Clean Air Act for all primary air pollutants except particulate and ozone (hydrocarbons).

The wastewater at Ivorydale is discharged into the sanitary sewer for treatment at the Mill Creek Wastewater treatment plant operated by the Metropolitan Sewer District of Greater Cincinnati (MSD). The typical load for the treatment plant is 120 million gallons per day (MGD) and the treatment plant accepts wastewater from residential, commercial, and industrial customers. The wastewater flow from Ivorydale is 4 MGD, which is 3% of the volume to MSD. The manufacture of olestra will increase this volume by 1 MGD. The storm water which falls on the plant property is collected then discharged into an MSD combined sewer system which drains heavy storm overflows into the Mill Creek.

Solid wastes (non-hazardous) from the plant are disposed to the ELDA Recycling and Disposal Facility landfill (Cincinnati, OH) operated by Waste Management Inc. Approximately 500 cubic yards per day of nonhazardous solid wastes from the Ivorydale plant are disposed of at the ELDA landfill. This waste volume accounts for 14% of the total material received by ELDA each day. Solid waste generated from the production of olestra will increase the total volume of plant solid waste being disposed of at the ELDA landfill by about 3% (15 cubic yards per day). Waste minimization and recycling will be practiced as economically feasible. The introduction, fate and effects of materials emitted as a result of olestra manufacture are discussed in the Sections of this document titled "Olestra manufacture".

The Procter & Gamble Jackson food plant is used to illustrate the environmental impact of olestra on a snack production location. The plant represents a reasonable worst-case scenario, because it is a large plant in a relatively small community. Also, snack processing generates more wastewater with higher concentrations of BOD and suspended solids than cracker processing because of a number of washings of the potatoes and corn prior to frying:

log mean:	Flow Ratio (gal/ton)	BOD_5 (lb/ton)	TSS (lb/ton)
Cookies and crackers (1)	387	2.16	1.25
Potato chips (2)	1407	18.5	21.1
Tortilla chips (2)	4878	59.4	72.1
Corn chips (2)	2883	70.4	59.8

(1) Source: Draft Development Document for Effluent Limitations Guidelines and New Source Performance Standards for the Miscellaneous Foods and Beverages Point Source Category. Prepared by Environmental Science and Engineering, Inc., 2/75, for USEPA.

(2) Source: Development Document for Interim Final and Proposed Effluent Limitations Guidelines and New Source Performance Standards for the Fruits, Vegetables and Specialties Segment of the Canned and Preserved Fruits and Vegetables Point Source Category, 10/75, USEPA.

The county in which the Jackson plant is located (Madison County) is designated as attainment for all primary air pollutants.

The wastewater at Jackson is discharged into a wastewater treatment plant operated by The Jackson Utility Division. The typical load for the treatment plant is 8 MGD, and the treatment plant accepts wastewater from residential, commercial, and industrial customers. The wastewater flow from Jackson is 0.3 MGD, which is 4% of the volume of the Jackson Utility Division's treatment plant. The production of snack foods using olestra will not have a significant impact on this discharge volume. Storm water which falls on the plant property is separated by dike systems that ultimately discharge either into the Forked Deer River or into the publicly owned treatment works (POTW).

Solid wastes (nonhazardous) from the Jackson plant are disposed of at the Jackson/Madison County Landfill (Jackson, Tennessee) operated by the county. Approximately 230 tons per month of nonhazardous solid waste from the Jackson plant are disposed of at the Jackson/Madison County Landfill. This waste volume accounts for less than 5% of the total material received by the county landfill each day. Solid waste generated from the production of olestra snack foods will increase the total volume of plant waste by about 130 tons per month. This is a 57% increase in plant solid waste being landfilled, which calculates to a 2% increase in total materials going into the Jackson landfill. Waste minimization and composting will be practiced as economically feasible. The introduction, fate and effects of materials emitted as a result of production of olestra snacks at Jackson are discussed in the Sections of this document titled "Snack production".

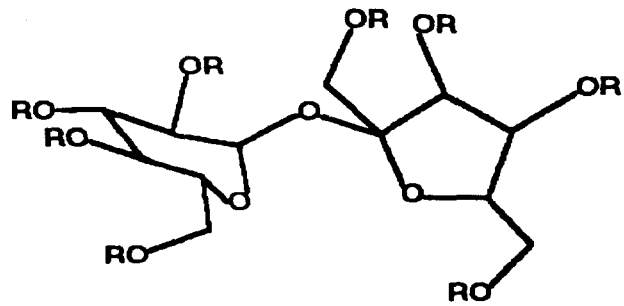
Normal consumption of olestra will be through human ingestion of consumer products containing olestra. By far, the most significant release of olestra will occur via excretion of human wastes and will involve the environments contiguous to cesspools/septic tanks and POTW. Disposal will also include consumer wastes, i.e., discarded food products containing olestra.

5. Identification of chemical substances that are the subject of the proposed action:
Nomenclature: Olestra

Olestra is a mixture of the hexa- to octaesters of sucrose with the naturally occurring fatty acids obtained from edible fats and oils.

Molecular weight: 2400 daltons (average)

Structural Formula: The representative structural formula for typical mixtures of olestra is:



Where R is a fatty acid substituted in six, seven, or eight of the available positions and H- in the rest.

Physical Description: Olestra is a fat-like material that resembles ordinary triglycerides in its physical properties. These properties may be varied through the selection of the fatty acids that are used for esterification. Olestra can range from a near liquid to a solid at environmental temperatures (20°C) depending on the degree of unsaturation of the fatty acid moieties (olestra composition specifications provided on next page).

For environmental fate and effects testing, the liquid olestra samples were approximately 80% (± 10) unsaturated while the solid olestra samples were approximately 65% (± 10) saturated. In comparison, the olestra composition specifications (next page) define an unsaturation upper limit of 83% and a saturation upper limit of 75%. The rationale for how the data obtained provide reasonable assurance that the range of olestras commercially available are environmentally safe is discussed in Format Item 6.

The solubility of olestra in various solvents is similar to that of triglycerides. Olestra is insoluble in water and soluble in organic solvents such as hexane, tetrahydrofuran, ethylene dibromide, ether, chloroform and oils. Olestra can be converted to fatty acids and sucrose by acid hydrolysis. By a similar process, triglycerides can be hydrolyzed to fatty acids.

Additives: Vitamin E as d-α-tocopherol acetate. Conventional fats and oils post-processing additives may also be used.

Olestra Specifications:

Major Constituents:	Total octa-, hepta- and heptaesters	≥ 97%
	Octaesters	≥ 70%
	Unsaturated fatty acid content	25-83%
	Saturated fatty acid content	≤ 75%
	C_{16}+C_{18} fatty acids	≥ 78%
	C_{20} and longer fatty acids	≤ 20%
Minor Constituents:	Hexaesters	≤ 1.0%
	Penta- and lower esters	≤ 0.5%
	C_{12}+C_{14} fatty acids	≤ 1.0%
	Free fatty acids	≤ 0.5%
	Total available methanol*	≤ 300 ppm
	Heavy metals as lead	≤ 10 ppm
	Lead	≤ 0.1 ppm
	Arsenic	≤ 1 ppm
Viscosity:	Stiffness	≥ 50 kiloPascals/sec

* Includes residual methyl esters and methanol

Changes with Heating: Olestra will undergo heating during snack production (i.e., frying). Detailed analytical characterization of olestra and triglyceride heated under conditions more severe than those used in production of savory snacks shows that the same chemical changes occur in both materials. No new components were formed in heated olestra which were not also present in heated triglycerides (as the glyceride analog). In addition, it was shown that unheated olestra, used in the environmental studies, contained nearly all of the components present in heated olestra.

The primary changes which occur upon heating olestra and triglycerides are oxidation of fatty acid side chains, hydrolysis of the ester bonds, and formation of polymer, most (>80%) of which is dimer. The viscosity of both olestra and triglycerides increases slightly after heating due to the presence of the polymer and as result of increased hydrogen bonding of the oxidized fatty acid side chains (see Procter & Gamble Heated Olestra Submission to the FDA; 10/29/90). The changes that occur with heating olestra during snack production should not significantly alter the treatability, fate including biodegradation rate, or toxicity potential of olestra. The conclusions of the environmental testing program therefore apply to olestra which has been heated during snack production.

6. Introduction of substances into the environment

Table 6-1 (page 7) describes the substances expected to be emitted to the environment as a result of the approval and use of olestra in savory snacks. The flowchart in Table 6-2 (page 8) describes the fate of olestra as a result of its manufacture, use in the production of snacks and consumption by consumers and the introduction of materials to the environment.

The amounts of olestra manufactured and used in snack production in Table 6-2 (page 8) were back-calculated from consumer consumption, assuming that all snack production facilities have waste streams similar to Jackson:

502 million lb/yr x (100% + 5.0% waste oil + 0.24% air + 0.5% waste snacks + 0.14% POTW)
= 502 million lb/yr x 105.88% = 532 million lb/yr to snack manufacture

532 million lb/yr x (100% + 0.5% sewer + 1.5% soap sludge + 0.5% landfill)
= 532 million lb/yr x 102.5% = 545 million lb/yr olestra manufactured

Unless stated otherwise in this environmental assessment, we have conservatively assumed that the total olestra volume is in addition to, rather than substituting for, the current volume of triglycerides consumed in snack food production.

The specifications provided on page 5 (Format Item 5) show that approval is being sought for olestra compositions ranging from near liquid (maximum 83% unsaturation) to solid (maximum of 75% saturation) at room temperature. The snack applications petitioned for will likely use compositions which contain 20-30% saturated fatty acids and are semi-solid at room temperature. Although this form of olestra was not tested in the early environmental studies, the results obtained provide the means to assess its potential environmental impact because this product falls within the fatty acid saturation range of the physical forms tested.

These results also provide the means to assess the potential environmental impact of solid olestras within the commercial specifications (saturation of 75%) even though the solid olestras tested had a saturation of about 65% (± 10). This is because the magnitude of difference in saturation is small enough to not substantially affect its environmental fate and impact. Olestras with either 65% or 75% saturation will both be solid at environmental temperatures (20°C) with similar melting points (about 42°C and 48°C, respectively). Given that there is no significant difference in sorption to sludge solids when the percent of saturation increased 3-fold (from 20% saturation in liquid olestra to 65% saturation in solid olestra) (see 6.b.ii.1, page 19), we conclude that a 10% increase in saturation (from 65% to 75%) will have no significant impact on olestra's affinity to sludge solids. Thus, both will be highly sorbed to sludge solids and added to soil via sludge amendment. We have demonstrated that solid olestra is biodegradable in soil with a half-life of 88 days (see 7.b.iii.2, page 26; and 7.c.iii.1, page 30). Increasing the saturated fatty acid content by 10% may increase this rate slightly but not to the extent that the material would accumulate in the environment. We conclude that the results presented in the EA support approval for the entire range of olestras as defined in the FAP.

TABLE 6-1

SUMMARY CHART OF SUBSTANCES EXPECTED TO BE EMITTED TO THE ENVIRONMENT

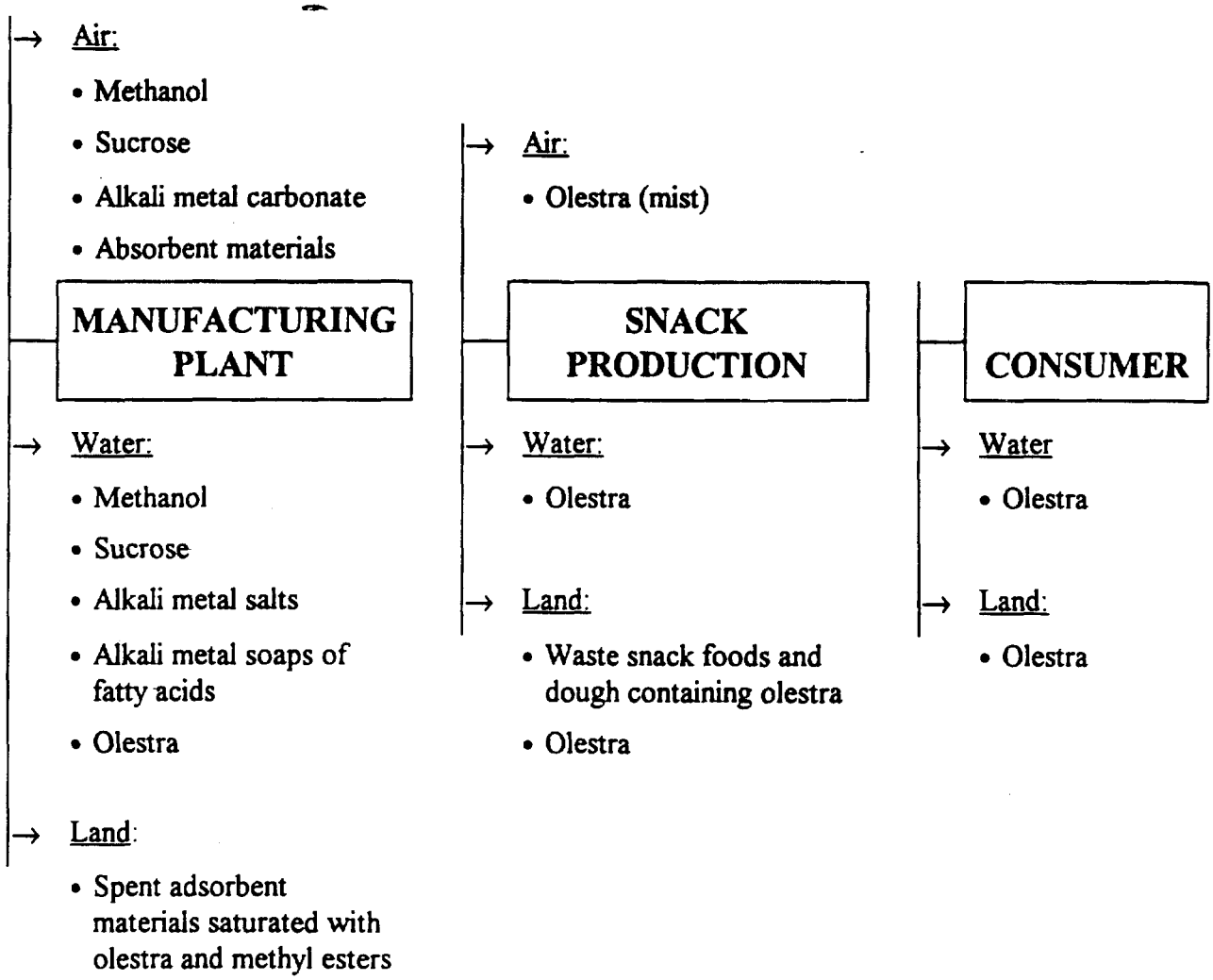
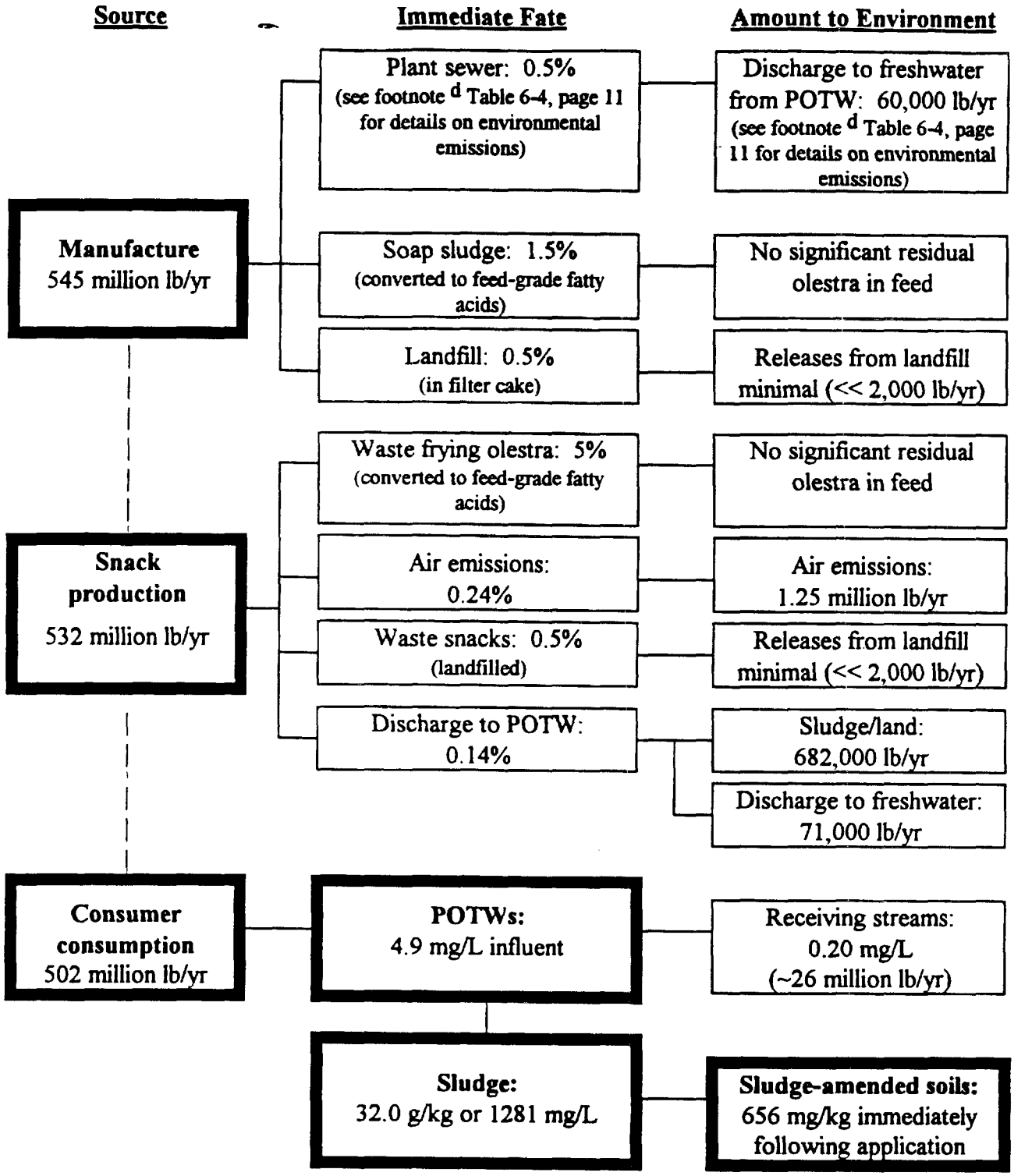


TABLE 6-2

Olestra Fate Flowchart



a. Sources

i. Olestra manufacture

All the raw materials used in the manufacture of olestra are commonly used or manufactured materials. For example, methanol is the 22nd most commonly produced chemical in the U.S. (C&EN, 1990). Sucrose is common table sugar. Potassium carbonate is commonly known as potash. The use of these materials in the production of olestra will not substantially increase existing background levels of these materials in the environment. Manufacture of olestra will be carried out in compliance with all federal, state, and local regulations and will include use of collection and containment devices to conform to these regulations. The Ivorydale Plant has six wastewater discharge points to the MSD sewer system, 48 permitted air emission sources, and 1 storm water discharge point to the Mill Creek. A formal process exists within the plant to identify, track, and correct the root cause of any permit exceedance. The past year's permit compliance record indicates that the Plant was in compliance >99% of the time. The Plant is currently in compliance with all the provisions of the permits listed below and local environmental ordinances that apply.

The permits that apply to the olestra operation at the Ivorydale site are:

- Air Emission Permit: Ohio EPA SW District Office, Source ID# 1431390903, olestra emission points: 36A, 36B, and 36C.
- Wastewater Discharge Permit: #MIL-048 issued by the Metropolitan Sewer District to cover the 6 discharge points from the site, olestra discharge point: S (which includes olestra, and industrial chemicals).
- Storm Water Discharge permit: Ohio General Permit #OHR000452 -- Storm Water Pollution Prevention.

The site (RCRA ID#: OHD092818368) has no RCRA Treatment, Storage (>90 days), or Disposal (TSD) facilities, and is not required to have a permit.

Approval of olestra will have no effect on compliance with current requirements. Anticipated production levels on approval have been included in these permits, and they have been permitted so that limits will be met on start-up when olestra is approved. The appropriate air emission control and wastewater pretreatment equipment has been approved by the Ohio EPA, and installed to protect the environment. Control devices used to assure compliance with federal, state, and local emission standards will include bag house dust collectors, cyclonic separators, surface condensers, scrubbers, gravity separators, the local POTW, and off-site incineration equipment.

Based on their expected use, the substances which could be emitted and/or discharged as a result of manufacturing can be found in Table 6-3 (page 10). None of these substances are considered to be sources of ecotoxicological hazard at the levels anticipated. The materials used in the manufacture of olestra will be emitted to the environment through a variety of means (Table 6-4, page 11). Dry materials such as sucrose and the various catalysts and absorbent compounds produce dust when handled. Minimal amounts of these dusts pass through control equipment and are

emitted to the atmosphere. The methanol scrubbers are 99.9% efficient, thus some minor amounts of methanol will be emitted to the atmosphere.

TABLE 6-3

SUBSTANCES EXPECTED TO BE EMITTED
DURING THE MANUFACTURING OF OLESTRA

SUBSTANCE NAME	CHEMICAL ABSTRACTS REGISTRY NUMBER
1. Methanol	67-56-1
2. Sucrose	57-50-1
3. Alkali metal salts	
Sodium Carbonate	497-19-8
Potassium Carbonate	584-08-7
Potassium Sulfate	7778-80-5
Sodium Sulfate	7757-82-6
Citrate salts, primarily Potassium Citrate	866-84-2
4. Adsorbent materials[a]	NA[b]
5. Alkali Metal Soaps of Fatty Acids	NA
6. Methyl Esters	NA
7. Olestra	NA

[a]"Adsorbent materials" refers to standard adsorbent materials used in edible oil processing such as bleaching earth, silica gel and filter aid.

[b]Not available.

TABLE 6-4

QUANTITIES OF MATERIAL EXPECTED TO ENTER THE ENVIRONMENT AS A RESULT OF THE MANUFACTURING OF OLESTRA

	SUBSTANCE NAME	RELEASE MEDIA	ESTIMATED AMOUNT (Tons/yr)
1.	Methanol	Air	17 [a]
		Water	16
2.	Sucrose	Air	12 [b]
		Water	Minimal (<<1)
3.	Alkali Metal Carbonate	Air	5 [b]
		Water	Minimal (<<1)
4.	Adsorbent Materials	Air	5 [b]
5.	Spent Adsorbent Materials, Saturated with Olestra and Methyl Esters	Land	Minimal (<<1) [c]
6.	Alkali Metal Soaps of Fatty Acids	Water	350
7.	Olestra	Water	30 [d]
8.	Alkali Metal Sulfates	Water	6,150 [e]
9.	Citrate Salts	Water	2,136

[a]Or to comply with the Clean Air Act of 1990.

[b]This is an exaggerated estimate of the amounts which could be released given current controls. These emission levels are unlikely to be present in practice because the economic value of the losses would exceed the cost to control emissions more tightly.

[c]~0.5% (i.e., 2.7 million lbs./yr or 1360 Tons/yr) of the olestra manufactured will be landfilled in spent adsorbent materials. Since olestra is not mobile in soil, minimal amounts of olestra are expected to enter the environment from these landfills.

[d]~0.5% (i.e., 2.7 million lbs./yr or 1360 Tons/yr) of the olestra manufactured will enter manufacturing site wastewater where it will be separated into two waste streams. One waste stream (fat trap collection) will yield 2.1 million lbs/yr (i.e., ~0.39%) which will be hydrolyzed to fatty acids. The remaining waste stream (POTW influent) will yield 600,000 lbs./yr (i.e., ~0.11%), with about 90% of this amount (i.e., 540,000 lbs./yr) being sorbed to sludge solids. This calculation assumes all olestra will be manufactured in Cincinnati, and in Cincinnati (where the production plant is located) sludge is burned and thus is not released to the environment. The remaining 10% of the POTW influent (i.e., 60,000 lbs./yr) of nonsorbed olestra is released to the environment in POTW effluent.

[e]From the hydrolysis of manufacturing waste streams to convert them to animal feed.

Wastewater from the manufacturing process will contain primarily water soluble materials such as sucrose, methanol and alkali metal salts (primary sodium and potassium sulfates). Sucrose and methanol are readily biodegradable, and the salts are commonly released in industrial effluent. The amounts of these compounds discharged to the local POTW will not inhibit sewage treatment or natural biodegradation (Grady and Lim, 1980; Verschueren, 1983). Minor amounts will be released into the environment from the POTW as a discharge to freshwater. (The POTW incinerates its sludge.) Table 6-4 summarizes the expected emissions of raw manufacturing materials. These releases to the environment are not expected to cause a noticeable increase over the background levels of these materials.

Additional liquids and semi-solids from the manufacturing process include fatty acids, soap, esters and olestra. These waste streams, as appropriate, will be hydrolyzed to fatty acid for use in animal feeds. About 1.5% of the olestra from manufacture will go to soap sludge and will be converted to feed-grade fatty acids. The process involves placing olestra in a dilute acidic solution, which causes the fatty acids to split off the sucrose and float to the top. After neutralization, the aqueous mixture containing alkali metal sulfate will be discarded to the local POTW. The acid hydrolysis process reduces the level of olestra to near or below the detection limit (< 1%) in the finished fatty acids. The resulting fatty acids will be sold for use in animal feed.

This hydrolysis process has been developed on a commercial scale by Cochran Corporation, Memphis, TN. Cochran received approval from the Association of American Feed Control Officials (AAFCO) in August, 1993 in the form of a definition for use of hydrolyzed sucrose polyesters in animal feed. William Price, Ph.D., Acting Director, Division of Animal Feeds, FDA Center for Veterinary Medicine (CVM), reviewed the information submitted and concluded that CVM has no objections to the tentative definition as long as the amount of unhydrolyzed olestra in the hydrolyzed sucrose polyester product is less than 2% (2/18/93 letter to Harley Hathaway, Cochran Corporation). Longer-term, the increased supply of spent olestra should be sufficient to justify the investment by other companies in developing similar capabilities.

Alkali metal sulfates will be generated by the use of H_2SO_4 in this hydrolysis process. The methyl esters that are not recycled in the manufacturing process or landfilled with the spent adsorbent materials will be used in animal feed or for other industrial programs. Methyl esters are an AAFCO-approved feed ingredient under Definition 33.4. Small amounts of emulsified esters and olestra will be discharged for treatment at the POTW. Since the esters will be hydrolyzed to fatty acids in the wastewater and neutralized to soaps, they are considered alkali metal soaps in the rest of this document.

The manufacturing plant sewer will have a gravity separator (fat trap) to capture a majority of the olestra that enters the wastewater through washing of olestra, wash down of equipment, and minor drips and leaks. The olestra captured will be converted to fatty acids through the hydrolysis process. Small quantities of olestra (approximately 195 mg/L in the Ivorydale effluent) will remain suspended in the wastewater and flow to the POTW for treatment. Studies have shown that about 90% of the olestra processed by POTWs will be sorbed to solids and collected as sludge. In Cincinnati, where the production plant is located, sludge is burned and thus olestra

sorbed to solids is not released to the environment. The remainder (about 10% of influent) is released in wastewater.

Spent adsorbent material will be saturated with olestra and methyl esters. This material will be landfilled in the ELDA Recycling and Disposal Facility landfill, operated by Waste Management, Inc., Cincinnati, OH, as a solid, as is currently practiced for similar materials from the manufacture of shortening and oils. Waste minimization and recycling will be practiced as economically feasible, as is being done in the shortening and oil industry. All process and storage areas will be provided with spill protection to minimize the potential for releases to the terrestrial and aquatic environment.

Throughout this EA, putting materials into landfills is not considered a release to the environment (42 U.S.C. § 9601 Sec. 101(8)). Only those materials which leave the landfill through percolation of water, volatilization, etc. are included as a release. No releases of olestra to the environment are expected because olestra is not mobile in soil (see Section 7.c.iii.2, page 32) and is not volatile, and thus will be effectively entombed in the landfill.

In addition, landfilling via state-of-the-art controlled sanitary landfills which meet the design criteria in 40 CFR § 258.40 are technically not releases to the environment because landfilled material is covered with dirt daily, and water which percolates through the landfill is collected and treated.

The olestra-containing materials that are landfilled (0.5% of total manufacture or about 2.7 million lbs./yr or 1,400 Tons/yr, Table 6.2) will not result in a meaningful increase (only 0.001%) in the 131 million Tons/year of landfilled U.S. municipal solid waste (Franklin, 1988). Since olestra does not migrate in soil and is non-toxic to plants and soil invertebrates and microbes, no adverse impact on the landfill is expected (see Sections 7.c.iii.2, page 32, and 8.b.ii, page 35).

The Ivorydale manufacturing facility will comply with all applicable environmental regulations as follows (see 6.a.i., page 8, for permit and compliance status):

- Air emissions will be controlled in compliance with Title 37, Chapters 3704 of the Ohio Revised Code and Title 3745, Chapter 3745, -21, -35, and -77 of the Ohio Administrative Code regarding permitting and operation of air emission sources in Ohio, including Title V permits.
- Liquid discharges will be to the local POTW and will be in compliance with all local discharge regulations, and permit requirements as directed by Title 3745, Chapter 3 of the Ohio Administrative Code.
- Solid wastes will be disposed in EPA-approved landfills and incinerators in compliance with Ohio EPA requirements specified in Title 3745, Chapter 27 of the Ohio Administration Code.
- Any waste disposal occurring outside the State of Ohio will be in accordance with all federal, state and local laws and regulations which apply.

All manufacturing areas used for the production of olestra will be designed and operated to comply with applicable OSHA regulations contained in 29 CFR 1910. Monitoring of the work area to determine occupational exposure will be carried out, and areas made to conform to all Permissible Exposure Limits (PEL's) according to OSHA Air Contaminants Regulations in 29 CFR 1910.1000.

Spills of olestra during transportation from the manufacturing facility to the snack production facility will be no different than that of any other edible oil spill in terms of frequency, clean-up and impact on the exposed area. The United States Department of Transportation in its interim final rule regarding oil spill prevention and response plans (Federal Register 58(114): 33302-33306, June 16, 1993) states that comprehensive response plans and spill prevention measures are required for shipments of bulk packaging containing nonpetroleum oil in quantities greater than 42,000 gallons. The DOT has determined that it is unnecessary to require any response plans or impose any prevention requirements with respect to nonpetroleum oils in quantities of 42,000 gallons or less, based on a finding that nonpetroleum oils appear to possess a lower level of aquatic toxicity than petroleum oils. Spill response will be the same for olestra as for other edible oils, i.e., absorbent booms and mats for liquids and shoveling for solids, with subsequent recovery or disposal in a sanitary landfill. Both liquid and solid olestra recovered from a spill can be hydrolyzed into sucrose and fatty acids. Information on proper disposal will accompany shipments as part of the MSDS. No long-term impact on the exposed area is expected because olestra is not toxic, does not contain volatiles, and will biodegrade with time.

ii. Snack production

Materials emitted to the environment through the production of snacks and chips will be olestra and rejected batches of olestra chips and other snack foods (Table 6-1, page 7). The Procter & Gamble Jackson food plant is used to illustrate the potential environmental impact of olestra on a worst-case snack production location because it is a large plant in a relatively small community, and because the processes used for producing chips from dried potatoes generate more waste than those used for frying traditional snacks or baking crackers. This EA assumes that all of the triglyceride used in snack food production at the Jackson plant is converted to olestra, i.e., 45 million lbs./yr of the 532 million lbs./yr (about 8.5%) of the total olestra used in snacks. Extrapolation of Jackson waste streams to total snack production thus results in worst-case volumes for materials that could enter the environment.

The frying process used to make savory snacks results in air emissions of olestra particulate. This particulate is expected to be the same size and quantity as that resulting from the use of existing frying oils. Emission testing of existing fryer stacks at the Jackson plant shows that 53 Tons/year of particulate (Table 6.5, page 17), assumed to be oil, are emitted, which is equivalent to about 0.2% of the 22,500 Tons/yr of triglyceride used at the Jackson plant. This air emission rate is considerably lower than the allowable permit rates.

Spent frying oils from snack production and any off quality olestra from manufacturing will be hydrolyzed into digestible fatty acids which can be fed to animals or used for

industrial purposes. The resulting aqueous by-product containing alkali metal sulfate will be discharged to the local POTW.

Assuming worst-case Jackson processes, about 5% of the olestra destined for snack production will end up as waste oil, virtually all of which will be converted to fatty acids for use in animal feed. Snack production facilities, such as Jackson, will ship waste olestra to a processor, such as Cochran Corp., much as they do now with triglyceride waste. Based on the nutritive value of the resultant fatty acid and the processing costs, it is estimated that wasted olestra frying oil will have a value of $0.04 to $0.07/lb versus approximately $0.11/lb for triglyceride "yellow grease". To assure unhydrolyzed olestra will not enter animal feed, Procter & Gamble has requested (March 31, 1994) that the final regulation be amended to state the following: Bulk labels of olestra, and shipping papers transmitting bulk olestra intended for food processing, must bear a caution "Olestra cannot be added to animal feed. Fatty acids obtained from fully hydrolyzed olestra are suitable for animal feed use." We will also provide information to companies who purchase olestra that it cannot be directly introduced into the animal food chain, that it must be must be hydrolyzed first, and will put them in contact with Cochran Corp. or other processors.

Another disposal option is to burn the waste oil as a fuel (Dawson, 1990). Currently, 23 U.S. commercial cement kilns and 6 municipal "waste-to-energy-incinerators" use various types of waste oil as fuel. When burned, olestra yields ~1.7×10^4 BTU/lb, well above the $1.0\text{-}1.2 \times 10^4$ BTU/lb typically provided by kiln fuels. Several environmental service companies have used olestra in this type of application, and found it to be an excellent and clean source of energy.

We conclude that substantial amounts of waste olestra oil will not be landfilled. Sale of waste olestra for processing into feed-grade fatty acids is economically attractive and shipment to a processor who can hydrolyze the waste olestra is similar to current means of disposal for spent oils. Use as a fuel will also be economically preferable to solidifying and landfilling.

Fats/oils/grease (FOG) are discharged in the Jackson plant effluent through wash down of equipment and minor drips and leaks. With the use of a gravity separator (fat trap), the plant captures a majority of this material, and the olestra in this trap will be converted to fatty acids by the hydrolysis process. Results in Table 6.5, page 17, show that 32 Tons/yr of olestra will remain in the wastewater (2.4 mg/L in the Jackson discharge) to be treated at the local POTW. About 29 Tons/yr (90% of the olestra in effluent) will be sorbed to solids and added to soil as POTW sludge. The remaining 3 Tons/yr will be released in wastewater.

The effluent standards for the manufacture of snacks (corn chips, potato chips and tortilla chips) are covered under the Specialties subcategory of the EPA "Development Document for Interim Final and Proposed Effluent Limitations Guidelines and New Source Performance Standards for the Fruits, Vegetables and Specialties segment of the Canned and Preserved Fruits and Vegetables Point Source Category (October, 1975)." According to this document, most of the snack processing facilities which would use olestra discharge to municipal treatment systems (Dev. Doc. p. 473), as P&G's Jackson

plant does. For the plants which treat their own wastewater, the best practicable control technology currently available, which is required by 33 USC § 1311(b)(2)(e), is biological treatment, either aerated or aerobic lagoons or activated sludge. Air flotation is suggested with activated sludge for potato chips and corn chips (Dev. Doc. p. 464). This process would result in a discharge into receiving streams of up to 2 mg/L, and sludge concentrations of up to 13 g olestra/kg dry sludge. This sludge concentration is similar to the 15.6 g/kg estimated for P&G's Jackson plant in Exhibit 9 and thus is covered by the Jackson assessment.

During the frying process, fatty acids are created as one of the breakdown products of olestra. The pH of the wastewater discharge is neutralized with sodium hydroxide which converts the fatty acids to soaps. The quantity and types of soaps produced will be similar to those produced by the current triglyceride frying process, and therefore are not included in this assessment.

Waste chips and snacks will be landfilled. As discussed on page 13, this is not considered a release to the environment.

Table 6-5 (page 17) summarizes the expected emissions of materials from snack production.

The Jackson snack foods production facility will comply with all applicable environmental regulations as follows:

- Air emissions will be controlled in compliance with Title 68 Chapter 25 of the Tennessee Code Annotated; with the Tennessee Air Pollution Control Regulations Chapters 1200, -3, -7, and -9 regarding permitting; and operating process equipment and with any new requirements resulting from the Clean Air Act of 1990.

- Liquid discharges will be to the local POTW operated by the Jackson Utility Division and will be in compliance with all local discharge regulations, and permit requirements as directed by Title 69 Chapter 3 of the Tennessee Code.

- Solid wastes will be disposed in EPA-approved landfills in compliance with requirements specified in Title 68 Chapter 31 of the Tennessee Code.

- Any waste disposal occurring outside the State of Tennessee will be in accordance with all federal, state, and local laws and regulations which apply.

All manufacturing areas used for the production of olestra snacks will be designed and operated to comply with applicable OSHA regulations contained in 29 CFR 1910. Monitoring of the work area to determine occupational exposure will be carried out, and areas made to conform to all Permissible Exposure Limits (PEL's) according to OSHA Air Contaminants Regulations in 29 CFR 1910.1000.

TABLE 6-5

QUANTITIES OF MATERIAL EXPECTED TO ENTER THE ENVIRONMENT AS A RESULT OF THE PRODUCTION OF OLESTRA SNACKS AT THE P&G JACKSON PLANT

	MAXIMUM RELEASED SUBSTANCE NAME	RELEASE MEDIA	ESTIMATED AMOUNT (Tons/Year)
1.	Olestra	Air	53
		Water	3
		Land	29*
2.	Waste snacks and doughs containing olestra	Land	<< 1**

*Or 2.4 mg olestra/L in the influent to the Jackson POTW. Release occurs through land application of POTW sludge to agricultural land.

**Up to 0.5% of the olestra used in snack manufacture will be landfilled as waste snacks and doughs (1,300 tons/year of olestra), but minimal releases to the environment are expected as a result of this means of disposal.

iii. Olestra consumption

The maximum consumption of olestra, as a food additive for national distribution, is projected to be 502 million pounds per year (Exhibit 1). The additive will be used as a replacement for fats and oils in the preparation of savory snacks. The major route of olestra introduction into the environment will be as a component of domestic and municipal wastewater, primarily in human feces (Table 6-2, page 8). The key environmental compartments for olestra will be similar to those of other fats, oils and greases (FOG) commonly found in municipal wastewater, namely terrestrial via land application of sludge and to a lesser degree aquatic settings. Because olestra is not volatile, air will not be an important compartment for the material.

Numerous environmental studies were conducted to assess the exposure, fate and potential adverse effects of olestra. Table 6-6 (page 18) lists the studies which were chosen to test opposite ends of the range of potential environmental forms (liquid and solid at environmental temperatures). Appendix 2 (page 80) identifies the study reports by FAP volume number and date of submission. Copies of each of these reports are attached.

Table 6-6: Olestra Environmental Studies*

	Liquid Olestra (80 ± 10% unsaturation)	Solid Olestra (65 ± 10% saturation)
Treatability		
Primary wastewater settling	x	x
Adsorption to primary sewage solids	x	x
Removal in semi-continuous activated sludge	x	
Removal in continuous activated sludge	x	
Sludge dewatering	x	
Fate		
Biodegradation in activated sludge	x	
Biodegradation in soil	x	x
Mobility in soil	x	
Fish bioconcentration	x	
Effects		
Anaerobic digester inhibition	x	x
Acute toxicity to aquatic and soil bacteria, algae, daphnids and fish	x	
Earthworm toxicity	x	x
Seedling toxicity		x

*The FAP requests approval of a range of olestra compositions (see Format Item 5, page 5) whose physical forms at environmental temperatures (20°C) range from primarily near liquid (unsaturation ≤ 83%) to solid (saturation ≤ 75%). Key studies were conducted with representative extremes of the formulation to assess the exposure, fate and potential adverse effects of olestra. Some studies were conducted with both forms to establish at least one direct comparison of treatability, of fate, or of toxicity. Either the liquid or the solid form was chosen for the remainder of the studies based on the ability to deliver the material to a particular test system, and a judgment that the physical form could possibly make a significant difference in treatability, fate or toxicity.

Key treatability tests, primary settling and anaerobic digester inhibition, were conducted with both liquid and solid olestra to establish the absence of affects across the range of olestra composition. Removal studies in activated sludge and sludge dewatering tests were conducted with only liquid olestra because the key treatability studies established that the physical form of olestra has no impact on olestra's strong affinity for solids. This indicates that the effects of liquid olestra on secondary removal and sludge dewatering processes are predictive for solid olestra as well. Key biodegradation tests were conducted with both liquid and solid compositions in soil because soil is the primary compartment olestra will enter. Biodegradation of liquid olestra was determined in activated sludge to provide perspective on the potential for olestra to degrade during wastewater treatment. However, in the Environmental Assessment we have assumed no biodegradation occurs during wastewater treatment, thus there was no reason to determine the biodegradation rate of solid olestra in activated sludge. Soil mobility, fish bioconcentration and acute toxicity tests in aquatic and soil bacteria, algae, daphnids and fish were tested with the form most likely to migrate in soil and be dispersed in water, liquid olestra. Earthworm toxicity was evaluated with both liquid and solid olestra to assure that potential differences in toxicity following ingestion were included. Seedling growth was evaluated with the solid olestra because the form is more slowly degraded; thus exposure to seedlings would be higher and more constant.

b. Olestra concentrations

i. Influent wastewater concentrations

Estimates of the levels of olestra expected in its key environmental compartments are based on methods described by Holman (1981) and Rapaport (1988). The expected maximum concentration in municipal wastewater is 5 mg/L (Exhibit 2). Olestra will therefore comprise only a small fraction of the 50-150 mg/L of FOG typically found in municipal wastewater (Metcalf and Eddy, 1979).

The concentration of olestra in domestic wastewater influent treated on-site will be approximately 15.5 mg/L, depending upon household size and the dietary habits of individual consumers. [Based on a family of 4 generating a 200 L/person/day wastewater flow to septic tank (Withee, 1975) and consuming 3.1 g/person/day olestra (Exhibit 2)]. This is not a significant increase above the 94 mg/L average measured levels of FOG in septic tank influent (Canter and Knox, 1985).

ii. Treatability during wastewater treatment

Treatability studies focused on the removal of olestra during primary (1) and secondary (2) wastewater treatment. These studies were conducted in either model primary clarifiers or model continuous activated sludge (CAS) systems having an aeration basin and secondary clarifier. Both types of laboratory model systems were designed, constructed and operated to mimic full-scale municipal wastewater treatment processes. Previous research on numerous consumer chemicals has demonstrated the applicability of these model systems.

During the treatability studies described below, ^{14}C-radiolabeled olestra was added to raw municipal sewage being fed to the appropriate treatment system (primary or secondary). To estimate the removal of olestra during each process, influent and effluent levels of radioactivity were measured. Mass balances of radioactivity were calculated to estimate mass recoveries, or to determine the extent of partitioning of the chemical onto sewage or activated sludge solids.

1) Primary wastewater treatment

Studies of primary treatment (settling) were conducted with both the liquid and solid forms of olestra and with a commercially available triglyceride. In the first study, liquid olestra was mixed with human feces and immediately added to municipal sewage being fed to model clarifiers. The concentration of olestra in the sewage was 2.18 mg/L. The removal of suspended solids during the test was 63% while olestra removal was 23% (Exhibit 3). In the second study, 0.054 or 0.77 mg/L of liquid olestra (to bracket the dispersability limit of 0.09) was pre-contacted with municipal sewage overnight (approximately 18 hours) prior to the removal test. This pre-contact period allowed time for the chemical to interact with the sewage and sorb to the suspended solids, simulating travel in the sewer before reaching the sewage treatment plant. Results (Exhibit 4) demonstrated that greater than 95% of the olestra was associated with total suspended solids in the

7. Fate of emitted substances in the environment

a. Air

i. Emissions from olestra manufacture

All sources of particulate and volatile emissions to the environment will be fitted with control devices to minimize releases and meet all permit requirements. Thus only very small amounts of the following materials are expected to be emitted (Table 6-4, page 11).

Methanol -- Methanol is the only volatile organic compound (VOC) used in the manufacture of olestra. Due to the low volumes and relatively low photochemical reactivity, emission of methanol to the atmosphere will have little effect on photochemical oxidation and production of ozone (U.S. Department of Health, Education and Welfare, 1970). Washout is expected to be the major mechanism for methanol removal from the atmosphere.

Sucrose, Alkali Metal Carbonate, Adsorbent Materials -- Emissions of the particulates of these compounds to the atmosphere will be removed through two mechanisms: washout and settling by gravity. The effects of the particulate will be minimized by atmospheric dispersion. Only a very small amount of these materials are expected to be emitted as particulates.

ii. Emissions from snack production

Olestra -- Air emissions of olestra particulate are expected to be the same size and quantity as current triglyceride emissions. These particulates will be removed through two mechanisms: washout and settling by gravity.

b. Freshwater, estuarine, and marine ecosystems

i. Discharges from olestra manufacture

There will be no direct discharge of materials from the manufacturing process (i.e., Ivorydale) into estuarine or marine environments. Discharges into the freshwater environment will occur indirectly through the discharge from the local POTW, or through atmospheric scrubbing during rainfalls. These discharges will be small based on the amounts expected to be discharged to the POTW or emitted to the atmosphere (see Table 6-4, page 11).

The pathway to freshwater environments is described below for each material used:

Olestra -- Removal of olestra in the POTW is expected to be greater than 90%. The maximum expected increase in olestra in the POTW effluent will be 50 µg/L, resulting in less than 0.1 µg/L increase in concentration of olestra in the Ohio River due to manufacturing.

Sucrose -- This material will find its way into freshwater environments through three means: 1) washout during rainfalls; 2) in the discharge from Ivorydale's local POTW

to the Ohio River; and 3) in the discharge from Cochran's hydrolysis process to its POTW which empties into the Mississippi River. Sucrose is readily biodegradable. Any amount of sucrose not treated by MSD will be diluted by the Ohio and Mississippi Rivers with their average flows of 88 billion gallons per day (Ohio River Valley Water Sanitation Commission, 1990) and 305 billion gallons per day respectively. The concentration of sucrose in the final effluent will not inhibit the natural in-stream biodegradation processes.

Alkali Metal Soaps of Fatty Acids -- These materials will find their way to freshwater environments through the discharge from MSD. Removal rates of fatty acids are between 79% and >99% (Shedroff and Green, 1990). The maximum expected increase of these materials from the manufacture of olestra in the Cincinnati POTW effluent will be 0.4 mg/L, resulting in a 0.5 µg/L increase in the Ohio River. The maximum expected increase in concentration of these materials from Cochran's conversion of waste frying oils to feed-grade fatty acids in the Memphis POTW effluent will be 0.7 mg/L, resulting in a 0.2 µg/L increase in the Mississippi River. These minor increases in the concentration of fatty acids will not inhibit the natural in-stream biodegradation process.

Alkali Metal Salts -- These inorganic materials dissociate in water into non-hazardous sodium/potassium and citrate/sulfate/carbonate ions. These ionic species are naturally occurring in surface and ground water. These ions will react in the POTW, and some will be removed, but most are expected to pass through. The expected increase of citrate salts in the Cincinnati POTW effluent is 12 mg/L, resulting in a 16 µg/L increase in concentration in the Ohio River. The expected increase in the concentrations of sodium, potassium, sulfate and carbonate ions in the Memphis POTW effluent are 14 mg/L, 5.3 mg/L, 30 mg/L, and 14 mg/L respectively, resulting in increases in concentration in the Mississippi River of 3.3 µg/L, 1.3 µg/L, 7.3 µg/L and 3.5 µg/L respectively. These increases are less than 1% of background levels.

Methanol -- This organic material is readily biodegradable in the POTW. A 99% removal efficiency of methanol can be expected based on the EPA Treatability Database, version 3.0. The expected maximum increase in concentration of methanol will be 0.006 µg/L in the Ohio River from olestra manufacture and 0.005 µg/L in the Mississippi River from olestra hydrolysis. No impact to the ecosystem downstream of either of these POTWs is expected (Verschueren, 1983).

ii. Discharges from snack production

Olestra -- Removal by the POTW is expected to be greater than 90%. Olestra removed from the POTW in sludge will be applied to agricultural lands. Based on the discharges from the existing chip production process, the maximum expected concentration in the POTW's discharge to the South Fork of the Forked Deer River after treatment will be 260 µg/L.

iii. Discharges from consumption of olestra

1) Bioconcentration

The bioconcentration of olestra in fish was determined both theoretically and experimentally. The octanol/water partition coefficient of olestra was measured by a modification of the method described by Karickhoff and Brown (1979) using radiolabeled material, and found to be log K_{ow} = 3.55 [FAP 7A 3997, Volume 2, Test Report C1, study attached]. Using published relationships between partition coefficients and bioconcentration factors (BCF) i.e., log BCF = 0.76 log K_{ow}-0.23 (Lyman, Reehl and Rosenblatt, 1982), a theoretical BCF of approximately 290 can be calculated. However, the bioconcentration of large complex molecules is known to deviate from theoretical estimates of BCF since their structures prevent absorption by biological tissues (Zaroogian, et al, 1985; Esser and Moser, 1982). Olestra is not absorbed through the gut or cell walls because of its large size and steric properties, as well as its low aqueous solubility. As a result, olestra does not have the potential to bioconcentrate. Actual experimental measurements confirmed that olestra did not bioaccumulate in fish tissue [FAP 7A 3397, Volume 2, Test Report C2, study attached]. Bluegill (*Lepomis macrochirus*) were continuously exposed to radiolabeled liquid olestra (0.025 mg/L) for 28 days using a method described by Bishop and Maki (1980). During this period, no radioactivity was detected in samples of the fish tissue (BCF < 50 based on detection limit in fish).

2) Biodegradation

Olestra will leave the POTW sorbed to solids. Thus, its residence time in the water column will be similar to the solids, after which time it will settle and become part of the sediment. Although it is theoretically possible that some aquatic biodegradation may occur, our data are insufficient to conclude that appreciable aquatic biodegradation will occur within this time frame.

3) Sediment concentration

The maximum sediment concentration of olestra in "hot spots" below wastewater treatment plants is estimated to be 42 g/kg or 4.2% of solids (Exhibit 11). This concentration represents a theoretical worst-case scenario and can only occur where: 1) all of the suspended solids are contributed by the treatment plant at a level of 10 mg/L; 2) no biodegradation of the olestra occurs; 3) all of these solids settle and become sediment, with no mixing or movement to dilute the olestra; and 4) suspended solids comprise 100% of the benthic sediments, thus concentration on solids on a dry-weight basis is the same for both suspended solids and benthic sediments.

This set of assumptions is highly conservative because a number of natural conditions exist in aquatic systems that collectively will prevent olestra from reaching this theoretical maximum concentration. This conclusion is based upon the following considerations:

- Olestra-containing solids from the treatment plant will not be the only source of aquatic solids because aquatic solids also come from such natural sources as topsoil run-off from storm events, or turbation and erosion of sediments above the wastewater treatment plant.

- We have no data to support the conclusion that olestra will biodegrade anaerobically. However, biodegradation of olestra will occur in the oxygenated zones of sediments because:

  i) Aerobic microorganisms are metabolically capable of utilizing olestra as an energy source.

  The potential for olestra to biodegrade in aquatic environments was estimated in studies using microorganisms taken from activated sludge. In a CO_2 screening study using the method described by Gledhill (1975) and Larson (1979), liquid olestra concentrations ranging from 5 to 40 mg/L were added to a 1% suspension of activated sludge microorganisms. Biodegradation was determined by trapping evolved CO_2 in $Ba(OH)_2$ and titrating to measure the amount of CO_2 produced from the test chemical.

  Results from these screening studies showed that olestra is biodegradable by activated sludge microorganisms [FAP 7A 3997, Volume 2, Test Report DI, study attached]. The extent of biodegradation ranged from less than 30% to essentially complete biodegradation over a 42-day period. Dispersability problems at these high concentrations of olestra could contribute to the observed variability.

  To provide more definitive data on the biodegradation potential of olestra, studies were conducted at environmentally realistic levels (0.05 and 0.5 mg/L), using radiolabeled liquid olestra added to samples of activated sludge. The olestra was labeled on the sucrose moiety. Thus, evolved CO_2 would represent complete mineralization of the olestra. During incubation on a rotary shaker, evolved radioactive CO_2 was captured in base traps and quantified by liquid scintillation spectrometry. These studies showed that biodegradation of olestra was a relatively slow but steady process in which 30-40% of the material was converted to CO_2 after 49 days of exposure (Exhibit 12). A large fraction of remaining radiolabel was likely incorporated into microbial biomass. Concentration had no effect on biodegradation.

  Finally, microorganisms in sludge-amended soils have been shown to biodegrade olestra that is sorbed to solids (see Section 7.c.iii.1. of the EA, page 30). This shows that sorption does not interfere with the microbiological biodegradation of olestra.

ii) The aerobic microorganisms found in sludge and known to be capable of metabolizing olestra (see above) are also found in both POTW wastewater and oxygenated zones of sediment.

Microorganisms typically found in wastewater will be carried in the water column and ultimately inhabit ecological niches in sediments. This conclusion is consistent with gram-negative rod genera predominating in aquatic environments with *Escherichia*, *Enterobacter*, *Pseudomonas*, *Achromobacter*, *Flavobacterium*, and *Zoogloea* being the most frequently isolated (Atlas and Bartha 1987; Pelczar and Reid, 1972). Holt (1977) notes that the same *Zoogloea* species found in surface waters, both free-floating and attached to solid surfaces, also occur in wastewater treatment systems. Actinomycetes are widely distributed throughout the environment and include such genera as *Nocardia* in aquatic systems, where they play an important ecological role in the biodegradation of organic material (Atlas and Bartha 1987). Genera are also found in activated sludge processes and include *Arthrobacter*, *Corynebacterium*, *Mycobacterium*, *Nocardia*, and *Rhodoccus* (WCPF 1990).

Protozoans also may biodegrade olestra. Genera found in wastewater systems include, but are not limited to, *Amoeba*, *Parameacium*, *Didinium*, *Vorticella*, and *Bodo* (WPCF, 1990). Protozoans graze on phytoplankton and bacteria in aquatic ecosystems and have been hypothesized to be the most common and abundant of freshwater zooplankton (Margulis and Schwartz, 1988).

While differences in the density, diversity, and metabolic activity of biodegraders preclude assuming comparable biodegradation rates in all environments, most biodegradation post-wastewater treatment would be expected to occur in the aerobic zones of sediments since olestra will be present in this environment for a longer period of time than in the surface water.

- Mixing or movement of sediments occurs in free-flowing aquatic systems. Temporary stagnation of down-stream discharge pools may occasionally occur during periods of drought. However, drought is a temporary condition and thus not a constant environmental factor. These stream beds will be replenished by rain, wastewater treatment plant discharges, and run-off, all of which will promote sediment mixing and movement.

- Olestra will not accumulate or become concentrated in benthic sediments much beyond its maximum 4.2% concentration in suspended solids below wastewater treatment plants.

Sediments have three main components: 1) interstitial water; 2) inorganic material such as rock and shell fragments and mineral grains; and 3) organic matter (Power and Chapman, 1992). Assuming a steady suspended solids concentration of olestra of 4.2% below wastewater treatment plant discharges and no degradation of olestra, the cumulative sediment concentration of olestra from the settling of solids can only increase if the other components of the sediment are degraded. In such a scenario, olestra, over time, would represent a proportionally larger fraction of the total sediment mass. The water and inorganic solids of sediments can be reasonably expected to be inert and remain constant. However, it is conceivable that the background organic carbon fraction of the sediments could, through biological activity under ideal conditions, be mineralized to carbon dioxide and water and subsequently be lost from the sediment. If it is conservatively assumed that no biodegradation of olestra occurs in sediments and total degradation of background sediment organic carbon is achieved, the following equation would be a conservative predictor of the cumulative concentration of olestra in sediments:

$$\text{Olestra in sediments (g/kg)} = \frac{\text{olestra in settled solids (g/kg)}}{1.0 - \text{organic carbon fraction in sediments}}$$

Where settled solids conservatively account for 100% of new sediment introduction and the concentration of olestra in settled solids remains constant.

Using the conservatively estimated olestra concentration in solids of 4.2% (42 g/kg) and a sediment organic carbon fraction below an outfall of a POTW of 30% (Sommers et. al 1977), the above equation yields a cumulative olestra concentration in sediments of 60 g/kg or 6.0%. This estimate differs only slightly from the initial conservatively estimated solids concentration for olestra.

c. Terrestrial ecosystems

i. Releases from olestra manufacture

Spent adsorbent materials containing about 30% olestra and methyl esters from the manufacturing operation will be landfilled.

Alkali metal soaps will be converted to fatty acids for animal feed. Small amounts from the manufacturing operation may also be landfilled as solid waste.

Some of the raw materials released as air emissions will ultimately return to terrestrial environments via washout by rainfall.

Olestra from manufacture will not be released to the environment in POTW sludge because Cincinnati incinerates its sludge.

ii. Releases from snack production

Olestra -- Small quantities of olestra will be discharged in the Jackson plant wastewater for treatment at the local POTW. Most of this olestra (~90%) will end up in the sludge. The Jackson POTW applies their sludge to agricultural lands. Based on the assumptions and calculations used in Exhibits 9 and 10, the Jackson plant could add up to an additional 15.6 g/kg of olestra above the 32.0 g/kg contributed by human consumption. This could result in a maximum soil concentration of 976 mg/kg; i.e., 656 mg/kg contributed by consumer consumption plus 320 mg/kg by the snack production facility.

Waste chips and other olestra snacks will be recycled when possible. Those products that are not recycled will be landfilled as solid waste.

iii. Releases from consumption of olestra

As described in Section 6.b.iv. (page 23), approximately 90% of olestra entering municipal wastewater treatment will be released to terrestrial environments as a component of digested municipal sludge. An additional fraction of the material will enter terrestrial environments via septic tank tile fields, septate discharged to landfills or by direct disposal to sanitary landfills. Thus the terrestrial setting is the key compartment for olestra.

1) Biodegradation

The olestra compositions covered by FAP 7A 3997 have a range of physical and chemical properties which are primarily dependent on the degree of saturation of the fatty acid side chains. These differences result in olestras which range from predominantly liquid to solid at environmental temperatures. Therefore, representative extremes, a liquid and a solid, were tested for biodegradation. The liquid olestra study is included in Volume 2 of the petition as Test Report E1. The solid olestra study was submitted as Volume 65, 12/20/90, Olestra Aerobic Biodegradation.

Biodegradation assays were conducted in soil collected from a sludge-amended agricultural field to simulate the actual conditions under which olestra would reach the environment in sludge. Liquid olestra was spiked at 7.5, 75 and 750 ppm radiolabeled compound. Concentrations of 7.5 and 375 ppm of radiolabeled sample was used in the subsequent, solid olestra study. The liquid olestra was dosed in hexane to promote uniform distribution of an extremely hydrophobic substance. Solid olestra was dosed both as a hexane solution, and sonicated in water in an attempt to simulate a more environmentally realistic form. Radiolabeled CO_2 production was monitored by the method described by Ward and Larson (1989).

Olestra was biodegraded by soil microbial communities as evidenced by the disappearance of parent compound and the production of CO_2. Exhibit 13 shows CO_2 production data for ^{14}C sucrose-labeled liquid and solid olestra, and equimolar concentrations of two control substances, sucrose and stearic acid.

Both chemicals are structural subunits of olestra. All four materials were biodegraded in soil. Conversion of liquid olestra to CO_2 was approximately 50% during the course of the 66-day study. This represented essentially complete mineralization as judged by comparison to the sucrose control. Over the 386-day solid olestra study, approximately 45% of the radiolabel was recovered as CO_2, or essentially the same amount as observed with the liquid olestra. Based on a fit of the CO_2 data to a first-order kinetic model for biodegradation (Ward and Larson, 1989), the biodegradation rate of liquid olestra at 7.5, 75 and 750 ppm was comparable to the rate of biodegradation of its two naturally occurring subunits (Exhibit 14). In the solid olestra study, the biodegradation rates of the controls (i.e., approximately 7 day half-lives) were comparable to those in the liquid study (i.e., approximately 4 day half-lives), however, the first order degradation rate of solid olestra was slower than for liquid olestra, 88 and 10 day average half-lives, respectively.

In summary, both forms of olestra are aerobically biodegraded in soil. Olestra soil accumulation estimates can be based on the 10 day and 88 day half-lives and a loading rate of 656 mg/kg soil. Over the representative extremes of formulations tested the difference in the degradation rates does not significantly affect the steady-state olestra soil levels. It is estimated that only 0-6% (0 to 39 mg/kg) of the olestra would remain in the soil between annual sludge applications (calculations in Exhibit 15).

a) Heated olestra

The biodegradation potential, and subsequent estimates of steady state sludge-amended soil concentrations, are not likely to be significantly different for heated olestra. This is for several reasons:

- The small decreases in octa- and increases in hepta- and hexaester which result from heating have the potential to increase biodegradation rate because of greater ease of hydrolysis of the fatty acid side chains. It is unlikely, however, that these small changes in ester distribution will significantly increase biodegradation potential.

- The increases in polymer resulting from heating might have the potential to decrease the biodegradation rate due to larger molecular size. It is unlikely that this effect will be significant because most of the polymer is only dimer (> 80%), and the magnitude of such effects will be small because the fatty chains and ester bonds are almost as accessible as in the monomer.

- Alternatively, the increase in polymer might have the potential to increase the biodegradation rate because the presence of the polymer will disrupt the crystal structure in solid olestras, resulting in a more liquid form. It is unlikely that this effect will be significant because the levels of polymer are too low to significantly change the melting point. Any effect which did occur would be beneficial because the current assessment is based on the slower degrading, solid form.

- Biodegradation rates for heated olestra would have to be considerably slower for them to result in significant differences in the estimates of steady-state levels of olestra remaining in terrestrial environments. As an illustration, a 50% decrease in the biodegradation rate (i.e., from 88 days to 176 days) would only result in an increase in the maximum, post-sludge application concentration of 860 mg/kg soil (up from 695), an exposure that still falls well within the concentrations shown to not adversely affect terrestrial microbes, plants and animals (see 8.b.ii., page 35).

2) Mobility

The mobility of olestra in soil was measured using a laboratory soil column containing a Borden sand (collected from the University of Waterloo Groundwater Research Site in Borden, Ontario). Borden sand is a low clay/organic, highly porous material and represents somewhat of a "worst-case" system with the highest mobility potential. In other systems, which have lower porosity and contain higher amounts of clay and organic matter, chemicals will generally be less mobile. Test materials consisted of liquid olestra, a positive "mobile" control (stearic acid), and a "non-mobile" negative control (4500 MW polyacrylic acid). For each chemical, domestic wastewater containing radiolabeled test substance was fed to separate columns after the columns had received 90 pore volumes of simulated ground water to establish stable flow patterns. The mobility of the test materials was determined by collecting aliquots of the column effluent over time, and assaying for radioactivity. Characterization of the test columns using tritiated water and chloride tracers indicated that the test columns performed properly relative to previous soil mobility studies with Borden sand.

Results are shown in Exhibit 16. The graph shows the cumulative percentage of initial radiolabeled test substance measured in the column effluent during the course of the mobility study which lasted for 70 pore volumes over 69 days. Characterization of the test columns using tritiated water and chloride tracers indicated that the test columns performed properly relative to previous soil mobility studies with Borden sand.

Olestra exhibited little mobility in Borden sand (Exhibit 16). The graph shows the cumulative percentage of initial radiolabeled test substances measured in the column effluent during the course of the mobility study which lasted for 70 pore volumes over 69 days. During this period less than 1.2% of the chemical was released from the soil. Stearic acid was considerably more mobile, and polyacrylate was only slightly more mobile than the olestra. Approximately 22.7% of the stearic acid and 2.4% of the polyacrylate were mobilized during the study. These results for polyacrylate are consistent with previously conducted studies.

Although, there is no data to confirm the observed mobility of stearic acid relative to olestra and polyacrylate, its higher mobility relative to these materials is consistent with its chemical properties (e.g., low molecular size and absorptivity).

d. Fate Summary –

The results of the mobility and terrestrial biodegradation studies demonstrate that olestra will not be mobile or persistent in terrestrial settings. The biodegradation studies reported here show that across the range of liquid and solid forms, the material will biodegrade in waste treatment and terrestrial matrices. There is also good indirect evidence (i.e., CO_2 screening test and activated sludge study) that olestra will degrade in surface waters. Fish studies showed no bioaccumulation of olestra. Furthermore, since olestra shows little mobility in soil it has limited potential to contaminate ground water resources beneath sludge-amended soils or septic tank tile fields (see data summary - Appendix 3, page 81).

8. Environmental Effects of Released Substances

a. Olestra manufacture and snack production

As described in Sections 6 and 7, the amount of non-olestra materials in the environment will not substantially increase background levels, and therefore no effects are expected.

The amount of olestra entering the environment from manufacturing will be very small relative to that from consumer consumption. A maximum of 50 µg/L olestra will be in the local POTW's effluent, and all of their sludge (containing the balance of the olestra) is incinerated. Thus no adverse environmental effects are expected.

The contribution of a snack production facility to the levels of olestra in sludge-amended soil will be less than for a POTW treating olestra from consumer consumption. The highest soil levels would occur in those few areas where the local POTW would receive olestra from both consumer consumption and snack food production, and where the POTW sludge was soil applied. The Jackson production plant and Jackson, Tennessee POTW is an example of such a situation. The maximum soil concentration of olestra receiving Jackson POTW sludge is estimated to be 976 mg/kg. This includes 320 mg/kg olestra from the production plant and 656 mg/kg contributed by consumer consumption (calculation in Exhibit 10). These soil concentrations are less than the maximum olestra levels tested in the earthworm and seedling growth studies and thus are covered by the existing data and by the assessment in the following Section (8.b). No adverse effects are expected from the release of olestra by snack production plants.

b. Olestra consumption

i. Aquatic effects

1) Water column

Standard acute toxicity bioassays were conducted with liquid olestra at concentration of up to 1000 mg/L. The organisms tested were bacteria (mixed natural assemblage), algae (*Selenastrum capricomutum* and *Navicula seminulum*),

zooplankton (*Daphnia magna*) and fish (*Lepomis macrochirus*). Threshold effect levels and acute LC_{50} values were not reached at the highest level tested [FAP 7A 3997, Volume 2, Test Reports F1 - F4, studies attached].

Based on the estimated maximum river water concentration of 0.42 mg/L olestra and an acute no observed effect level of >1000 mg/L, it was concluded that olestra presents no hazard to aquatic life.

These studies did not directly address exposure via consumption, i.e., by ingestion of olestra-containing sediments. Exposure of aquatic species through ingestion of olestra-containing sediments rather than water dosing will not result in adverse effects because desorption of a non-absorbed, non-toxic material is not an issue. A substantial body of olestra data in other species indicates its lack of toxicity and uptake.

2) Sediments

EPA often uses data for fish and daphnids to estimate toxicity for benthic organisms. There is typically not a concern for sediment toxicity unless the chemical is seen to be toxic in water exposures. Because olestra doesn't display toxicity in water it also would not be expected to display toxicity in sediments.

When exposed in water, benthic organisms such as worms, insect larvae and amphipods used in sediment testing are comparably sensitive to the standard water column species used to derive the national water quality criteria (i.e., fish, daphnids, etc.) for most chemicals (Office of Water Regulations and Standards (OWRS) 1989 Briefing Report, Section 5). A substantial amount of data supports the fact that the concentration-response curve for biological effects is correlated to interstitial water (i.e., pore water) concentration (OWRS, Section 3.1 to 3.3). This is because benthic organisms are exposed primarily to chemicals in the aqueous phase of sediments and not to those in the sorbed phase (Adams et al., 1985). It is the pore water that is generally believed to be responsible for toxicity to sediment dwellers. Toxicity for benthic organisms is thus estimated by applying the same criteria as used for water, but adjusting the toxicity values for sorption and partitioning (OWRS, page 3).

Projected olestra levels in sediments will not be toxic to benthic organisms based on the approach discussed above. The calculations supporting this statement, taken from OWRS, pages 3 through 5, are provided in Exhibit 17. These calculations demonstrate that the maximum concentration of olestra in sediments, 42 g/kg or 4.2%, will not exceed the safe level of olestra in sediments, 19% (Exhibit 11).

Extensive long-term testing in mammalian species and earthworms, as well as an absence of absorption and bioconcentration, provides assurance that chronic toxicity will not occur. A question could be raised as to the relevance of the relatively short aquatic toxicity studies, i.e., was the olestra just slow in getting into the organisms? The substantial body of data on mammalian species supports

that olestra is a non-toxic material and would have no effects in longer studies. This was also demonstrated in the 28-day earthworm studies, where olestra had no adverse effects on the health of an invertebrate species exposed to it by ingestion at high levels (5,000 mg/kg soil; Exhibits 18 and 19). Absence of bioconcentration was demonstrated in the 28-day chronic bioconcentration study in which no residues of radiolabeled olestra were isolated from fish tissues (7.b.iii., page 26).

Long-term, olestra concentrations in sediments will be reduced by normal physical processes. Following a plant malfunction, olestra sorbed to solids would exit the wastewater treatment plant and move along with the solids. The very high solids concentration in influent wastewater will serve to dilute olestra concentrations in sediment. Because olestra does not reduce primary settling (6.b.ii, page 19), it will not impact the movement or settling of these suspended solids in waterways. Eventually these solids will settle out into the river/lake sediments and will move along with the sediment bed via scouring and redeposition. Mixing of concentrated wastewater solids with other solids will occur prior to sedimentation due to current flow and variations in sedimentation rates. Following sedimentation, further mixing will result from erosion and transportation of the sediments.

ii. Terrestrial effects

Terrestrial studies focused on the potential effects of the material on: 1) soil microorganisms, which carry out key nutrient cycling processes in soil; 2) six species of crop plants; and 3) earthworms, an indicator species for soil invertebrates.

1) Soil Microbes

The toxicity of olestra to natural soil microbial communities was assessed by measuring the effect of the additive on their ability to degrade a readily degradable, naturally occurring substrate (sucrose). Liquid olestra (7.5, 75 or 750 ppm) was added to samples of sludge-amended soil along with approximately 100 ppm of radiolabeled sucrose. The highest level of olestra tested was about 50% higher than the maximum concentration expected in sludge-amended soils, assuming a maximum usage level of 502 million lb/year.

CO_2 production from the sucrose was measured over time (Ward and Larson, 1989). Across the range tested, olestra had no effect on sucrose biodegradation (Exhibit 20). Thus it was concluded that the material poses no hazard to terrestrial microbial communities.

2) Seedling growth

Solid olestra was tested because it is the more slowly degraded form (half-life of 88 days versus 10 days for liquid olestra), thus resulting in predictions of somewhat higher steady-state soil levels. In fact, it has been suggested that compounds with half-lives less than 10 days are probably lost from a soil system before being accumulated by plants (Paterson et al., 1990).

Seedlings of six plant species (i.e., corn, cucumber, pinto bean, rye grass, soybean and wheat) were exposed to solid olestra at five concentrations from 220 mg/kg to 930 mg/kg dry soil for 21 days. Survival, shoot length, and dry root and shoot weight of seedlings were assessed. For perspective, a parallel seedling growth study was conducted with a commercially available triglyceride shortening having physical properties and fatty acid composition similar to the solid olestra.

No adverse olestra treatment-related effects were observed for five of the six species tested (Exhibit 21). Olestra treatment at levels above 220 mg/kg soil was associated with reduced root weights in pinto beans. Triglyceride treatment was associated with reduced growth parameters or survival in five of the six species at concentrations as low as 190 mg/kg. The effect of olestra on the root weights of pinto beans is unlikely to be the result of direct phytotoxicity. This is because olestra is unlikely to be taken up by plants due to its high affinity for sludge and soil solids which will make it less available, and its high molecular weight (~2400) and low water solubility which will limit plants' ability to absorb it (Paterson et al., 1990 and Dr. Michael Overcash, North Carolina State University, personal communication, 2/11/91).

We conclude that the reduced root weight was the result of indirect toxicity as a consequence of decreased water transport capacity of the quartz sand treated with the hydrophobic test material. This would be expected from direct application of a hydrophobic material such as olestra to sand since water percolation would likely be decreased resulting in the indirect effect on root weight. An adverse effect on plant growth would not be expected to occur under realistic exposure conditions because olestra will be added to soil as part of sludge and not added directly to soil. Further evidence for the lack of direct phytotoxicity of olestra comes from the work of M. R. Overcash et al., 1994 in which olestra at 0-1000 mg/kg in soil alone or in sludge/soil mixtures had no effect on plant growth as measured by seed germination; plant height; and shoot and root weight of corn, fescue, wheat, and soybean, with seed production also assessed in the latter two.

3) Earthworm toxicity

The potential terrestrial toxicity of both liquid and solid olestra to soil invertebrates was assessed. This direct comparison of the toxicity of the two forms seemed appropriate because uptake via ingestion was possible and would maximize the likelihood of being able to evaluate systemic toxicity. Earthworms (*Lumbricus terrestris*) were exposed to concentrations as high as 5000 mg/kg of the test substance for 28 days. Behavior (burrowing), incidence of abnormalities, and mortality were similar for controls and olestra exposed earthworms (Exhibits 18 and 19). All test groups showed some weight gain, although the worms exposed to the highest concentrations (2,500 and 5,000 mg/kg) liquid olestra gained significantly more weight than the low dose and control groups. Based on the results of these tests, it is concluded that neither liquid nor solid olestra adversely affected the earthworms at concentrations as high as 5,000 mg/kg, which is the highest concentration tested and at least 10 times the maximum soil concentration expected at maximum olestra usage. Further, the test data do not suggest that

concentrations greater than 5,000 mg/kg would produce an adverse effect on earthworm survival or behavior.

4) Soil physical and chemical properties

Olestra will have no adverse effects on soil physical or chemical properties. Given that olestra will be a relatively minor component of sludge (~5% of solids), sludge itself will impart most if not all of the physical and chemical effects on soils. We have concluded that the reduced pinto bean weight observed in the seedling growth study was the result of decreased water transport due to treating soil directly with a hydrophobic test material. This hydrophobic effect is not relevant to assessing the effect of olestra on soil properties under realistic conditions because under realistic conditions olestra will be added as a minor component of sludge.

It is unlikely that olestra will have any effects on soil above those caused by sludge because sludge has a major impact on soil characteristics, olestra will be a minor component of sludge, and olestra's physical nature of hydrophobicity will produce effects on the physical nature of soil consistent with the effects that sludge produces. The major effects of sludge are to increase plant growth on unproductive soils through the nutrients supplied in the sludge and to improve the physical condition of many soils. Application of organic wastes to soils: 1) increases water storage capacity, reducing percolation losses of water and nutrients; and 2) decreases the water transmission parameters, enhancing surface irrigation efficiency. Organic matter is known to be hydrophobic in nature, and many of the favorable effects of sludge have been attributed to hydrophobicity (Kumar, et al., 1985; Guidi, et al., 1983). Any increases in sludge's initial water repellency do not translate into long-term differences in infiltration rates (Gupta, et al., 1977).

The most likely effect of olestra on soil would be a temporary increase in hydrophobicity, similar to the sludge itself. Even if olestra does increase the hydrophobicity of sludge, it will not have an adverse effect on the physical properties of soil. Direct effects on soil chemical properties are not expected because olestra is nonionic and hydrophobic. Indirect effects on chemical properties by sorbing and coating otherwise reactive surfaces are also not expected because olestra will preferentially sorb to organic and neutral inorganic surfaces rather than to the negatively charged, hydrophilic clay which is the key determinant of many soil chemical properties (Hillel, 1980).

iii. Wastewater treatment effects

Research on the potential impact of olestra on wastewater treatment centered on the effects of the material on key unit processes. In particular, research focused on those processes which have analogs in both the municipal and home treatment systems. Home systems (e.g., septic tanks) may have somewhat higher influent concentrations of olestra relative to municipal treatment facilities (our estimates are 5 mg/L in a POTW and 15.5 mg/L on site; see Section 6.b.i., page 19).

To assess the potential impact of olestra on the processes operating in municipal and home treatment systems, the effect of olestra was studied in the following: 1) primary treatment -- dynamic (continuous flow) and batch treatment; 2) secondary treatment -- activated sludge and sludge dewatering; and 3) anaerobic digestion. The results from these studies were combined with information on soil biodegradation, microbial toxicity and soil mobility to provide an overall assessment of the potential impact of olestra on municipal and home wastewater treatment.

1) Primary treatment

In an initial study, liquid olestra had a positive effect on primary settling and slightly increased the removal of total suspended solids (TSS) during dynamic and batch primary wastewater treatment. In the dynamic studies, raw municipal sewage containing up to 200 mg/L of olestra or soybean oil (pre-contacted overnight) was dosed to model clarifiers and the removal of suspended solids was monitored. No significant difference in the removal of suspended solids was observed at any level of either olestra or soybean oil (Exhibit 22).

In batch studies, the settleability of the solids in municipal sewage precontacted with up to 200 mg/L of olestra was measured. Settleability is defined as the percentage of solids which will settle in a batch column system after one hour (Standard Methods, 1985). Settleability of the sewage suspended solids increased approximately 10% as the concentration of olestra was increased from 0 to 200 mg/L (Exhibit 22). However this increase also occurred for the control oil (soybean) indicating that both materials had positive effects on settling.

In a subsequent dynamic settling study as mentioned earlier (Exhibit 5), the effects of both liquid and solid olestras on the removal of TSS and chemical oxygen demand were evaluated. Appropriate solid and liquid triglyceride controls were also included at concentrations up to 200 mg/L. Neither solid nor liquid olestra had inhibitory effects on the primary settling process, relative to undosed control units and to similar triglycerides. Removal of both liquid and solid olestra were much higher than the triglycerides and were similar to the TSS removal suggesting that olestra was associated with the solids in the removal process.

2) Secondary treatment

The effect of olestra on activated sludge treatment was assessed in CAS units. Concentrations ranging from 1 to 200 mg/L of liquid olestra or soybean oil were

added to municipal sewage entering several CAS systems. Samples of the influent and effluent were taken over a 5-day test period and analyzed for suspended solids and COD. The removal of solids and COD in the test units were compared to data obtained from a control unit which received no added chemical. After removal testing at each level of chemical, an aliquot of sludge was taken from the CAS units, stabilized with 100 mg/L $FeCl_3$ (Metcalf and Eddy, 1979), and tested for the effects of the test materials on sludge dewatering as described by Eckenfelder, Adams and Ford (1978). Two hundred ml of sludge were filtered through a Buchner funnel. The change in vacuum pressure during filtration and the total volume of water drawn from the sludge was monitored to determine if olestra or soybean oil adversely affected the dewatering characteristics of activated sludge.

Liquid olestra had no adverse impact on the removal of suspended solids during CAS treatment (Exhibit 23). Suspended solids removal in the control, olestra and soybean oil units was greater than 85 percent in all cases. A statistically significant increase in removal was observed at an olestra concentration of 200 mg/L. However, the increase was less than 7% higher than removal in the control unit.

The removal of COD in CAS units was not adversely affected by either olestra or soybean oil, except for several isolated cases which were showed no apparent dose response relationship (Exhibit 23). Olestra had no unique effect that was not also observed for soybean oil.

Neither liquid olestra nor soybean oil significantly altered the dewatering characteristics of activated sludge. Of the 200 ml total volume filtered during a dewatering test, all was recovered during filtration, and no changes were observed in vacuum pressure [FAP 7A 3997, Volume 2, Test Report B3, study attached].

3) Anaerobic digestion

Anaerobic digestion inhibition tests were performed to assess the potential impact of olestra on anaerobic digestion. In this test system, the primary indicator in determining inhibitory effects is a decrease in total gas production relative to the controls. In an early olestra study, cumulative gas production was measured over a 14-day period from sewage sludge containing up to 1,000 mg/L of liquid olestra. There was no change in total gas production (Exhibit 24) at levels less than or equal to 100 mg/L. At 1,000 mg/L, gas production was decreased by less than 10%, a change which is not regarded as practically significant based on the inherent variability of municipal digesters (Metcalf and Eddy, 1979).

In two subsequent parallel studies, the effects of liquid and solid olestra at concentrations of up to 10,000 mg/L were evaluated in lab-scale batch anaerobic digesters. In both studies, the effects of olestra and triglyceride were compared to positive and negative control concentrations of phenol at 250 and 1,500 mg/L, respectively. Both the liquid and solid olestra had no observed adverse effects at 10,000 mg/L, the highest concentrations tested. The triglyceride oil and shortening did not inhibit gas production. As expected, in both studies the

250 mg/L concentration of phenol had no inhibitory effect, while the 1,500 mg/L concentration did inhibit gas production (Exhibit 24).

4) Treatment plant malfunctions

Olestra will not have acute or chronic effects in waterways which receive large amounts of untreated wastewater solids because of its low toxicity. Olestra's aquatic acute no-observed effect level of > 1,000 mg/L (8.b.i, page 33) will not be exceeded even if raw sewage flowed directly into the waterways because the predicted maximum municipal wastewater concentration of olestra is only 4.9 mg/L (Exhibit 2).

Under high-flow conditions, olestra would enter receiving waters as a component of sewage in combined sewer overflows (CSOs). Although CSO discharges are highly variable, substantial dilution of sewage typically occurs (Tchobanoglous and Burton, 1991), with further subsequent dilution in the waterway from the excess water from contributories and land run-off. Under these dilution conditions, the likelihood of an acute impact is decreased even further than in the worst-case scenario above.

Under low or normal flow conditions, where high levels of wastewater solids are allowed to enter a waterway as the result of a permit violation, the safe level of olestra would also not be exceeded, although the sewage itself would have major impacts because the highest predicted concentration of olestra during the treatment process (1,029 mg/L in anaerobically digested sludge) still does not exceed the acute no observed effect level.

The absence of long-term effects in sediments is discussed in 8.b.i.2.

5) Potential for separation from solids during treatment

If the solids to which olestra is sorbed are degraded, olestra will sorb to other solids rather than separating to form a scum or cause mechanical problems.

Olestra is very hydrophobic (Section 5, page 5), sorbs strongly to solids in any system in which water is present and does not easily dissociate. Removals of olestra onto solids are higher than comparable triglycerides (6.b.ii., page 19), indicating that it is less likely to separate from solids than triglycerides.

Wastewater treatment studies demonstrate that separation of olestra from solids does not occur during the primary and secondary treatment process. During primary treatment (settling) studies, greater than 90% of the olestra was associated with the suspended solids and removal was approximately that of the solids (6.b.ii., page 19). Estimates of the sorption coefficient (K_d, the ratio of the mass on the solid phase to the mass in the liquid phase) ranged from 287,000 at 200 mg/L to 10,000 at 1500 mg/L TSS (Exhibit 6). During a secondary treatment study, greater than 95% of the olestra in the aeration chamber was associated with the sludge solids, and 73-74 % of the olestra in the effluent was contained on the solids (Exhibit 7).

Effects in other major secondary treatment processes should be similar to the activated sludge processes in the FAP studies because they exhibit similar solids removals (McAvoy, et al, 1993). Even in anaerobic digesters, substantial amounts of solids survive the digestion process (Sommers, 1977). More than 90% of the organic carbon and an even greater portion of other solids will survive digestion and remain available as sorption surfaces for olestra. Even if it were possible for a "superdegrader" to remove all of the organic carbon from the solids, such a process would also be very likely to degrade all of the olestra.

Even if olestra did not degrade, it will sorb to the inorganics which remain rather than separating. Olestra's ability to sorb to inorganics was demonstrated in a mobility study in which liquid olestra was applied to Borden sand, which is low clay/organic and highly porous. The olestra was even less mobile than the 4500 MW polyacrylic acid "non-mobile" negative control (Exhibit 16).

6) Domestic wastewater treated on site

Making the conservative assumption that olestra does not degrade anaerobically, olestra accumulation in septic tanks will not require more frequent pumping. The 15.5 mg/L olestra concentration in septic tank influent will be a relatively small proportion of the 94 mg/L FOG and 800 mg/L total solids entering septic tanks (6.b.i., page 19). Based on the anaerobic digester study, olestra will not interfere with the degradation of other materials in the tank (8.b.iii.3, page 39). Olestra will adhere to the solids and will settle with them into the sludge. Even if some olestra enters the scum layer, it will not cause operational problems because baffles protect against the scum being drawn into the tile field, keeping the scum in the tank until it is pumped. The amount of olestra which will accumulate in septic tanks, 9.4 kg (calculated in 6.b.ii.3, page 21; Canter & Knox, 1985), will be insignificant in a 750 gal (2839 L) tank and will not be sufficient to require more frequent pumping.

Olestra is unlikely to increase tile field failures in septic tanks. The primary causes of tile field failure are: 1) inadequate system design, primarily tile fields which are too small for the type of soil and loading rates; 2) hydraulic overloading; and 3) poor tank maintenance, which allows excessive amounts of solids to enter the field. Increased organic loadings do decrease tile field life (Siegrist and Boyle, 1987). However, the olestra in tank effluent (4.8 mg/L [6.b.ii.3., p. 21]; theoretical COD (14 mg/L) will be small enough, relative to typical organic effluent levels, that any effect would not be measurable. For example, typical COD levels in tank effluent are 300 mg/L, with a range of 25 to 780 mg/L (Canter & Knox, 1985). Olestra does not interfere with soil microbial communities (8.b.ii.1, page 35) and thus will not hinder the degradation of other substances in the effluent. Since olestra degrades aerobically and functioning tile fields are aerobic, it should not accumulate to a point where it will clog soil pores. Predicted steady-state concentrations of olestra in tile fields, calculated as shown in Exhibit 25, are 30.6 mg/kg for liquid olestra and 278 mg/kg for solid olestra.

iv. Heated olestra

The aquatic and terrestrial toxicity potential of the components present in heated olestra has been assessed because nearly all of these components were present in the heated olestra used in these tests. In addition, the known lack of environmental toxicity of triglycerides, many of which have been heated prior to introduction to the environment, supports the safety of the same components present in olestra.

c. Effects summary

Olestra is nontoxic at levels far in excess of those predicted for aquatic environments (Exhibit 8; predicted maximum stream level = 0.42 mg/L). Terrestrial species including soil microbes, earthworms and crop plants were not adversely affected by exposure to olestra at concentrations greater than the maximum expected in sludge-amended soils (Exhibit 15; predicted maximum soil level = 695 mg/kg). Moreover, biodegradation studies demonstrate that olestra will not persist in sludge-amended soils. From the standpoint of municipal treatment, levels up to 50-times higher than those expected in sewage produced no detrimental effects on primary or secondary wastewater treatment (see Exhibit 2; predicted maximum POTW influent levels = 4.9 mg/L). Effects on anaerobic digestion were tested up to 10-times the maximum levels expected in digested POTW sludge, with minimal effect (Exhibit 9; predicted maximum sludge level = 1281 mg/L). Olestra accumulation in septic tanks is not expected to require more frequent pumping because the accumulation in the tank will be insignificant and because olestra does not have adverse effects on settling or anaerobic digestion. Olestra is unlikely to increase tile field failures through increased organic loading because the amount of olestra in the effluent will be small relative to other organics, and olestra does not interfere with the metabolic activity of soil microbial communities.

9. Use of Resources and Energy

Manufacture of olestra will be carried out at an existing Procter & Gamble plant site covering approximately five acres of land. The production of every 100 pounds of olestra from methyl esters purchased from a supplier will consume approximately 0.75 pounds of adsorbent materials, 6×10^5 BTUs of coal, 4×10^4 BTUs of electricity and 5.6×10^4 BTUs of natural gas. Procter & Gamble operates one of the largest vegetable oil shortening manufacturing plants in the United States. Based on the operating experience of this facility, one pound of adsorbent, 1.85×10^5 BTUs of coal, 0.17×10^5 BTUs of electricity and 0.73×10^4 BTUs natural gas are required to produce 100 pounds of vegetable oil shortening. When the entire yearly production volume, 545 million pounds of olestra, is compared to an equivalent amount of vegetable oil shortening, a decrease in resources of 1.36 million lb/yr of adsorbent materials and an increase in energy of 2.65×10^{12} BTUs/yr will be result. This is equivalent to 442,000 barrels of crude oil/yr (assuming that on average a barrel of crude oil contains 6,000,000 BTUs).

It is possible, although unlikely, that some buyers may choose to dispose of spent olestra by landfilling. Sale of waste olestra for processing into feed-grade fatty acids is economically attractive and shipment to a processor who can hydrolyze the waste olestra is similar to current means of disposal for spent oils. Use as a fuel will also be economically preferable to solidifying and landfilling. Buyers who purchase large volumes of olestra are likely to avoid use of landfills because landfilling increases risk of future liability, is costly and has associated public relations issue. However, if a buyer did want to dispose of olestra oil in a landfill, the easiest and most likely means of solidifying the oil would be to mix it with a solid material such as natural earth or clay, or even solid triglyceride. Landfilling will not be discussed further since it is not an energy- or resource-intensive process relative to the disposal process we have assumed below.

In this assessment we have conservatively assumed that spent olestra will be disposed of by hydrolysis, which will require more energy than similarly disposing of spent vegetable oil due to increased processing and transportation costs. When the entire yearly volume of waste olestra is considered, 34.7 million lb/yr (8.15 million lb/yr in soap sludge from manufacturing facility plus 26.5 million lb/yr from snack production), the increase in energy used to dispose of olestra compared to that used to dispose of vegetable oil shortening is 6.25×10^9 BTUs/year. This is equivalent to 1042 barrels of crude oil/yr (assuming that on the average a barrel of crude oil contains 6,000,000 BTUs). In addition, average additional rail transportation energy use of $\sim 5 \times 10^9$ BTUs/yr will result.

This new material will be produced at an established manufacturing site on land which is currently being used for manufacture of other products. There will be no destruction of trees, wetlands, or other wildlife habitat to make room for manufacture of olestra. Therefore, there will be no issues regarding endangered or threatened species nor property listed in or eligible for listing in the Federal Register of Historic Places as a result of the proposed action.

10. Measures taken to Avoid or Mitigate Potential Adverse Environmental Impacts Associated with the Proposed Action

Additional measures which will be taken to avoid and/or mitigate releases to the environment include: 1) spill prctection around all liquid storage areas; 2) the use of settling basins to capture settleable and floatable materials; 3) secondary filters on the bag house dust control filters; 4) waste minimization and recycling as economically feasible; and 5) a strong corporate policy for the management of materials in an environmentally safe manner. Procter & Gamble's Environmental Quality Policy is in Exhibit 26. Manufacturing operations will be under the supervision of qualified engineers and managers. Procter & Gamble will continue to provide training for personnel on emergency actions in the event of accidental situations which might result in releases to the environment. An active maintenance program will also be implemented.

Based on the described environmental assessment of manufactured olestra, there will be no adverse environmental impacts. Thus no mitigation procedures beyond those described are required for the material.

11. Alternatives to the Proposed Action

No alternative actions are proposed based on the environmental assessment presented above.

12. List of Preparers

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Dr. Kenneth L. Dickson, Director and Regents Professor, Department of Biological Sciences, Division of Environmental Sciences, University of North Texas

13. Certification

The undersigned official certifies that the information presented is true, accurate and complete to the best of Procter & Gamble's knowledge.

Name: K.C. Triebwasser Title: Director, Regulatory and Clinical Development
Food and Beverage Products

Date: 4-5-95 Signature: Keith Triebwasser

14. References

Copies of referenced journal articles and selected other references are provided in the numbered tabs following the EA exhibits.

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EXHIBIT 1

Estimated Quantity of Olestra That Will Enter the Environment as a Result of Consumption of Savory Snacks.

3.1 g olestra/person/day[1]
x 80.6 % of population consuming snacks/crackers
x 365 days/year
x 250 million people in U.S. (U.S. Census Bureau 9/1/90)
= **2.28 x 10^{11} grams/year, or 502 ,000,000 pounds/year**

Assumptions:

Estimated daily intake (EDI) is used as a basis for environmental concentrations as a result of consumption of olestra savory snacks as described in Harrass et al. (1990). EDI assumes 100% olestra substitution for conventional frying oils in savory snacks.

An alternative method would have been to use snack market volumes. Based on information from the Snack Food Association and Nielsen's National Scantrack data, almost 4 billion pounds of snacks are marketed annually in the U.S. This represents just over 1 billion pounds of fats and oils.

It is not known how much of the difference between disappearance and intake estimates is due to differences in measuring techniques and how much represents waste snacks which enter the existing solid waste disposal stream. The volume of waste olestra snacks should be similar to current volumes of waste triglyceride snacks, most of which is believed to be landfilled. If all of the marketed volume of snacks are consumed, 500 million pounds per year of olestra would represent a 40% market share, which is a reasonable upper share expectation, given current shares of diet soft drinks and light beers.

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[1] Based on the intake estimates submitted May 26, 1993, adjusted upward by 10% as per the December 24, 1990 letter from John Gordon, FDA, to K. C. Triebwasser, P&G.

EXHIBIT 2

Predicted Maximum Municipal (C_{mw}) and Domestic (C_{dw}) Wastewater Concentrations for Olestra in Savory Snacks and Crackers.

C = X/Q[1] where: X = average consumption (mg/day)[2]

Q = average per capita sewage flow (507 liters/day)[3]

C_{mw} = 2.50×10^3 mg/day / 507 liters/day
= 4.93 mg olestra/liter

C_{dw} = 3.1×10^3 mg/day / 200 liters/day
= 15.5 mg olestra/liter

---

[1]After Metcalf and Eddy, 1979

[2]Average per capita consumption of olestra is 2.50 g/person/day: (3.1 g/person/day x 80.6 % of population consuming)

[3]After Holman, 1981.

EXHIBIT 3

Removal of Liquid Olestra During Primary Wastewater Treatment (No Pre-contact)*

Material mixed with human feces to a final olestra concentration of 2.18 mg/L.

Constituent	Removal (%)	Mass balance (%)
Suspended solids	63.0	94.0
Olestra	23.1	94.2

*FAP Volume 2, Test Report A1

EXHIBIT 4

Partitioning and Removal of Liquid Olestra During Primary Wastewater Treatment*

Olestra was pre-contacted with the municipal sewage for approximately 18 hours.

1. Partitioning into solids:

Olestra Conc. (mg/L)	Percent of Olestra in Influent	
	On solids (%)	In liquid
0.054	95.1	2.6
0.77	98.9	1.1

2. Removal:

Olestra Conc. (mg/L)	Suspended Solids (mean % + S.D.)	Olestra (mean % + S.D.)
0.054	71.8 + 1.0	61.8 + 2.5
0.77	70.0 + 0.8	66.3 + 1.6

*FAP Volume 2, Test Report A2

EXHIBIT 5

Removal and Effects of Liquid and Solid Olestra on Primary Settling.*

	Liquid Study		Solid Study	
	Olestra	Triglyceride	Olestra	Triglyceride
Test Substance Removal				
1 mg/L	53.7%	32.3%	87.2%	24.4%
1 mg/L	61.5%	59.9%	82.1%	32.2%
TSS Removal				
0 mg/L (control	60.5%	74.8%	82.4%	80.1%
1 mg/L	57.9%	68.9%	84.2%	76.6%
1 mg/L	59.3%	74.3%	84.8%	81.2%
10 mg/L	63.6%	72.1%	82.6%	77.2%
100 mg/L	79.3% s	86.3%	85.1%	85.0%
200 mg/L	66.5% s	67.6%	82.8%	83.9%
COD Removal				
0 mg/L (control)	60.5%	55.8%	70.5%	70.1%
1 mg/L	61.9%	54.1%	67.7%	64.9%
1 mg/L	64.2%	60.8% s	71.6%	74.5%
10 mg/L	62.4%	60.5%	69.8%	70.5%
100 mg/L	69.0% s	64.3%	80.5%	79.2% s
200 mg/L	68.3% s	49.1%	79.3%	79.0% s

*FAP supplemental submission, Volume 70, ... pg. 67 "a" ...

s statistically significant (versus control) at 90% confidence.

EXHIBIT 6

Adsorption of Liquid Olestra Onto Primary Sewage Solids.*

Solids Concentration (mg/L)	Initial Olestra Concentration (mg/L)	Sorption Coefficient (K_d)[1]
200	0.01	169,297
	0.05	352,411
	0.1	367,959
	1.0	257,542
	Mean	**287,000 ± 105,000**
700	0.01	33,038
	0.05	86,908
	0.1	84,956
	1.0	75,665
	Mean	**70,000 ± 24,000**
1500	0.05	6,619
	0.1	4,593
	1.0	10,649
	5.0	21,871
	10.0	8,783
	50.0	7,352
	Mean	**10,000 ± 6,000**

* FAP Volume 2, Test Report A3

[1] K_d is the ratio of the mass on the solid phase to the mass in the liquid phase.

EXHIBIT 7

Removal and Partitioning of Liquid Olestra During secondary Wastewater Treatment In Continuous Activated Sludge*

1. Removal:

Olestra Conc. (mg/L)	Overall Removal (%)[1]
0.06	84.0 ± 5.0
1.0	84.9 ± 11.4

2. Partitioning:

Olestra Conc. (mg/L)	Partitioning in Aeration Chamber (%)	
	In Liquid	On Solids
0.06	0.4 ± 0.2	98.7 ± 4.9
1.0	0.2 ± 0.1	95.5 ± 5.9

	Partitioning in Effluent (%)	
	In Liquid	On Solids
0.06	27.4 ± 5.8	74.3 ± 4.8
1.0	24.1 ± 6.0	72.8 ± 7.0

---

* FAP Volume 2, Test Report B2

[1] "System" includes that in aeration chamber and clarifier (primarily on solids).

EXHIBIT 8

Estimated Weighted Mean Concentration of Olestra in Municipal Effluent and Receiving Streams*

	Primary Treatment Removal of:	
	23%	65%
Final Effluent		
Maximum (C_{EP})	3.8 mg/L	1.8 mg/L
Minimum (C_{ES})	0.6 mg/L	0.3 mg/L
Average (C_{EA})	**1.4 mg/L**	**0.7 mg/L**
Receiving Streams	**0.42 mg/L**	**0.20 mg/L**

Final effluent concentrations are calculated as follows:

$C_{EP} = C_I(1-R')$

$C_{ES} = C_I(1-R')(1-R'')$

$C_{EA} = F_P(C_{EP}) + F_{AS}(C_{ES})$

Where:

- C_{EP} is the final effluent concentration with primary treatment
- C_{ES} is the final effluent concentration with primary and secondary (activated sludge) treatment
- C_{EA} is the average effluent concentration considering the fraction of POTWs with primary treatment and, in this case, the fraction with trickling filters, versus the faction with activated sludge treatment
- R' is the removal efficiency of primary treatment
- R" is the removal efficiency of activated sludge treatment
- C_I is the influent concentration of olestra
- F_P is the fraction of flow receiving primary treatment only
- F_{AS} is the fraction of flow receiving activated sludge treatment

*USTEST model is used to predict receiving stream concentrations.

EXHIBIT 8

(continued)

Assumptions:

- Olestra consumption is 502 million pounds per year, for an influent concentration, C_I, of 4.9 mg/L olestra (see Exhibit 2).
- The fraction of U.S. wastewater treatment flow receiving only primary treatment, F_P, is 4% (Rapaport, 1988).
- Primary removal, R', is 23% (see Exhibit 3) or 65% (see EA p. 20, last paragraph).
- The fraction of U.S. wastewater treatment flow receiving treatment in the trickling filter category (trickling filters, rotating biological contactors, oxidation ditches, stabilization ponds, lagoons) is 21% (Rapaport, 1988).
- Trickling filter removal is the same as primary removal and is, therefore, included in F_P.
- The fraction of U.S. wastewater treatment flow receiving activated sludge treatment, F_{AS}, is 75% (Rapaport, 1988).
- Secondary (activated sludge) removal, R", is 85% (see Exhibit 7).
- Receiving stream concentrations are reported as 90th percentile mean values as a function of the volume of POTW flow.

EXHIBIT 9

Predicted Maximum Concentration of Olestra in Digested Municipal Sludge (C_{ds}) Following Secondary Treatment

$$C_{ds} = C_{mw} (F_1/F_6) \times (R' + R'' - D') \times (1 - D'') \times 0.025$$

Where:

C_{mw} = concentration in municipal wastewater

F_1/F_6 = ratio of sewage sludge flow to sludge flow = 260

R' = removal in primary treatment = 65%[1]

R" = removal in secondary treatment = 35%[1]

D' = biodegradation in secondary treatment[2]

D" = removal in anaerobic digestion[3]

0.025 = conversion factor from mg/L to g/kg assuming a typical sludge solids concentration of 0.04 kg/L

C_{ds} = 4.93 mg/L (260) (0.65 + 0.35 - 0) (1-0) = 1281 mg/L x (0.025) = 32.0 g/kg

These calculations assume:

- [1]Efficiency of treatment reflects the conservative assumption that 100% of olestra from wastewater treatement ends up in sewage sludge (i.e., 65% in primary treatment (see page 20 of the EA, last paragraph) and 35% in secondary treatment)
- [2]No anaerobic degradation in digester
- [2,3]All removals are via adsorption; i.e., no biodegradation

---

The maximum concentration of olestra contributed by the Jackson plant (C_{jp}), assumes a plant wastewater concentration of 2.4 mg/L:

C_{jp} = 2.4 (260) (0.65 + 0.35 - 0) (1-0) (0.025)

C_{jp} = 15.6 g/kg

EXHIBIT 9

Predicted Maximum Concentration of Olestra in Digested Municipal Sludge (C_{ds}) Following Secondary Treatment

$$C_{ds} = C_{mw} (F_1/F_6) \times (R' + R'' - D') \times (1 - D'') \times 0.025$$

Where:

C_{mw} = concentration in municipal wastewater

F_1/F_6 = ratio of sewage sludge flow to sludge flow = 260

R' = removal in primary treatment = 65%[1]

R" = removal in secondary treatment = 35%[1]

D' = biodegradation in secondary treatment[2]

D" = removal in anaerobic digestion[3]

0.025 = conversion factor from mg/L to g/kg assuming a typical sludge solids concentration of 0.04 kg/L

C_{ds} = 4.93 mg/L (260) (0.65 + 0.35 - 0) (1-0) = 1281 mg/L x (0.025) = 32.0 g/kg

These calculations assume:

- [1]Efficiency of treatment reflects the conservative assumption that 100% of olestra from wastewater treatement ends up in sewage sludge (i.e., 65% in primary treatment (see page 20 of the EA, last paragraph) and 35% in secondary treatment)
- [2]No anaerobic degradation in digester
- [2,3]All removals are via adsorption; i.e., no biodegradation

---

The maximum concentration of olestra contributed by the Jackson plant (C_{jp}), assumes a plant wastewater concentration of 2.4 mg/L:

C_{jp} = 2.4 (260) (0.65 + 0.35 - 0) (1-0) (0.025)

C_{jp} = 15.6 g/kg

EXHIBIT 10

Initial Concentration of Olestra in Sludge-Amended Soil
(for typical consumer consumption)

C_{soil} = C_{ds} x Incorporation Factor

C_{soil} = 32.0 g/kg x 0.0205 x 1000 mg/kg
= **656 mg/kg (ppm)**

Where:

C_{ds} = concentration in digested sludge

$$\text{Incorporation factor} = \frac{\text{Annual Application Rate}}{\text{Incorporation Depth x Soil Bulk Density}}$$

Assumes:

- Maximum usage levels of olestra (502 million pounds per year)
- Application rate = 3.7 kg sludge/m^2/year [1]
- Incorporation depth = 15 cm = 0.15 m [2]
- Soil bulk density = 1200 kg/m^3 [1]

Calculation of the Jackson plant contribution to the concentration of olestra in sludge amended soil:

$C_{(j)soil}$ = 15.6 g/kg x 0.0205 x 1000 mg/kg
= **320 mg/kg (ppm)**

Total initial concentration of olestra in soil amended with sludge from the Jackson POTW (i.e., input from consumer consumption and production plant):

C_{soil} + $C_{(j)soil}$ = 656 mg/kg + 320 mg/kg = 976 mg/kg

---

[1]After EPA, 1978 and Harrass et al., 1990.

[2]After Holman, 1981 and Harrass et al., 1990

EXHIBIT 11

Maximum Concentration of Olestra in Sediments Below Wastewater Treatment Plant

	Primary Treatment Removal of:	
	23%	65%
Receiving stream concentration[1]	0.42 mg/L	0.20 mg/L
Concentration of suspended solids in stream[2]	10 - 100 mg/L	10 - 100 mg/L
Olestra concentration on solids, dry weight basis[3]	4.2 - 42 g/kg[4]	2.0 - 20 g/kg
Solids concentration in sediment[2]	0.5 - 2 kg/L	0.5 - 2 kg/L
Olestra concentration in sediment	2.1 - 84 g/L[5]	1.0 - 40 g/L

[1] From Exhibit 8

[2] Ambrose, 1988

[3] Assumptions:

- The wastewater treatment plant is the source of 100% of the solids in the stream. None of the solids are contributed by terrestrial materials, such as topsoil; runoff from storm events; or turbation and erosion of sediments above the wastewater treatment plants.
- 100% of the olestra is associated with solids.
- No biodegradation occurs.
- No resuspension, disturbances or other movement of sediments occurs which would have the effect of mixing sediments which are high in olestra with those containing lower concentrations.
- Suspended solids eventually comprise 100% of the benthic sediments; thus concentration on solids on a dry weight basis is the same for both suspended solids and benthic sediments.

[4] Worst-case example calculated as follows:

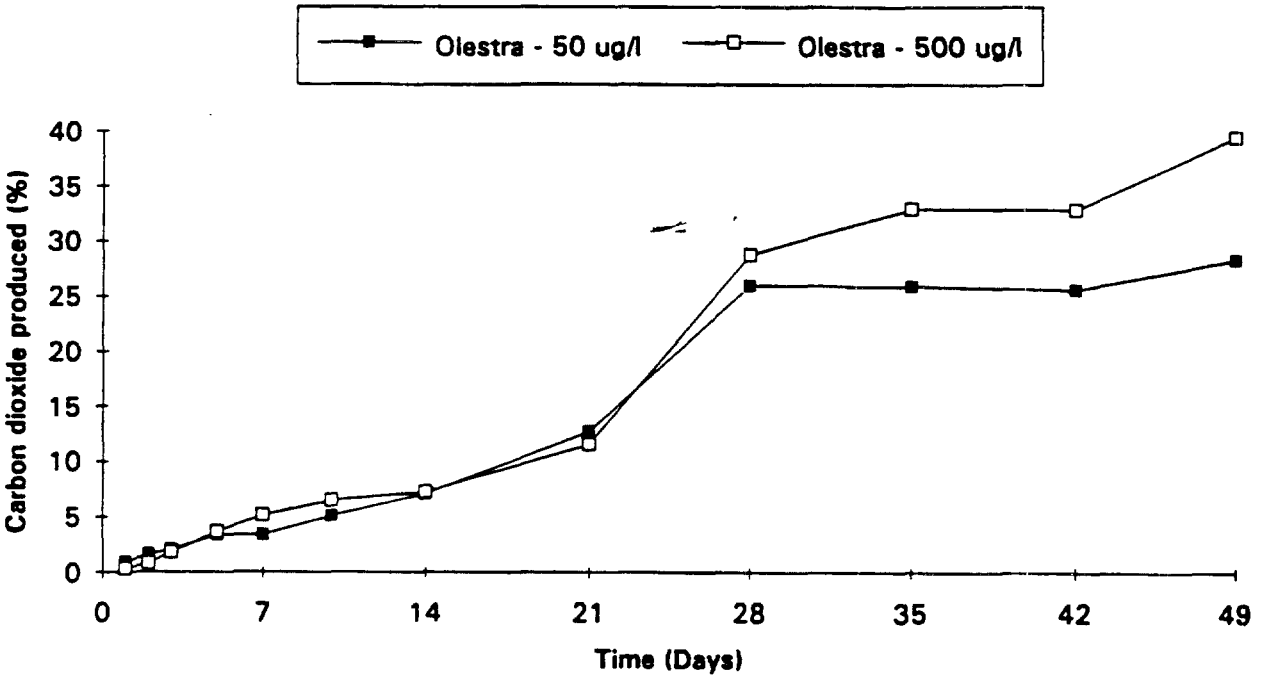
$$\frac{\text{0.42 mg/L olestra in stream}}{\text{10 mg/L solids in stream}} = \frac{\text{420 mg olestra}}{\text{10,000 mg solids}} = \frac{\text{42 g olestra}}{\text{kg solids}}$$

[5] Worst-case example calculated as follows:

$$\frac{\text{42 g olestra/kg solids}}{\text{0.5 kg/L solids in sediment}} = \text{84 g olestra/L}$$

EXHIBIT 12

Biodegradation of Olestra in Activated Sludge at Initial Concentrations of 50 and 500 µg/l*

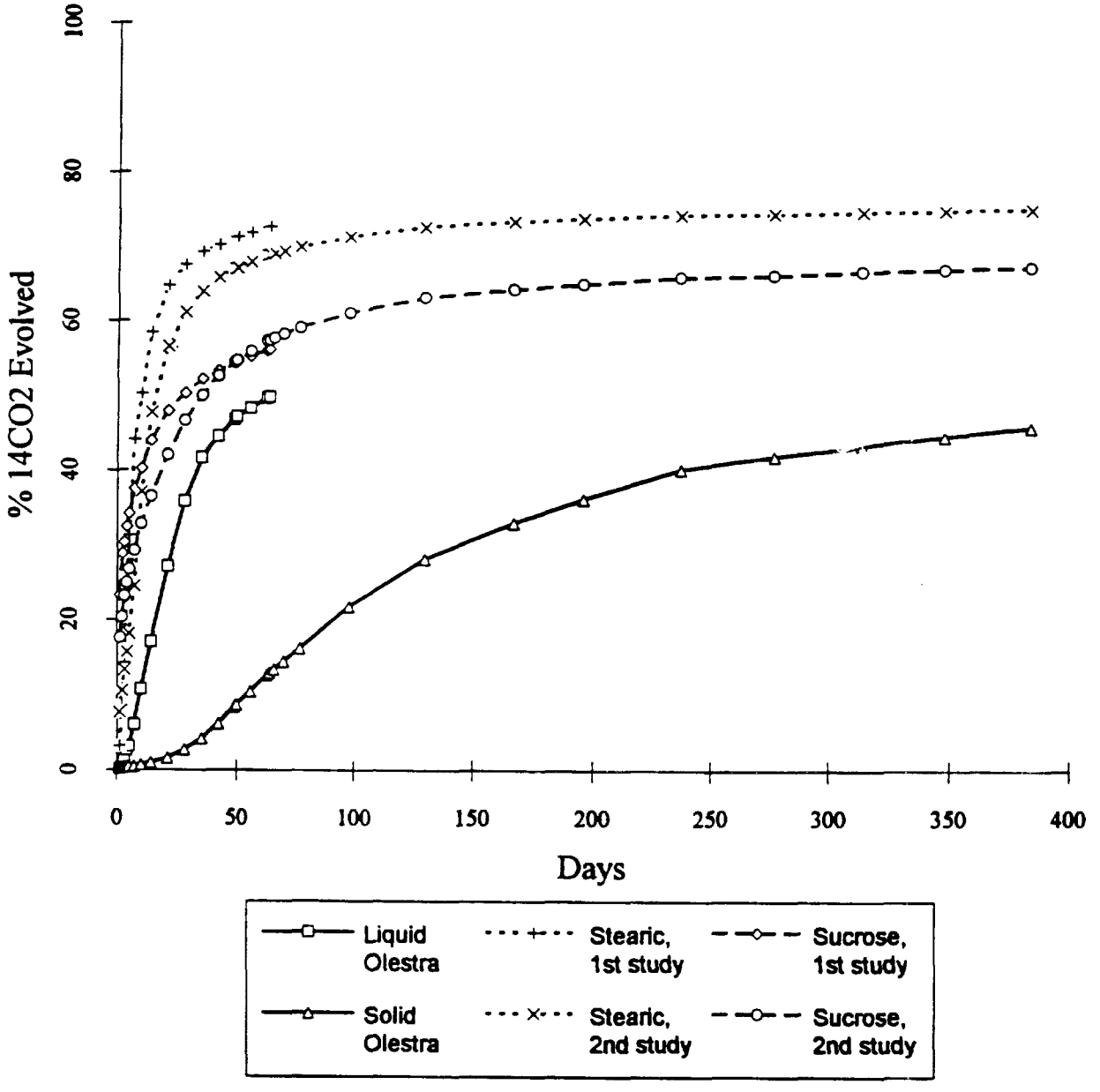


* FAP Volume 2, Test Report D2

EXHIBIT 13

Olestra Soil Biodegradation*

(Liquid and Solid Olestra, Stearic Acid and Sucrose)



* FAP Volume 2, Test Report E1 and FAP Supplemental Submission, Volume 65, 12/20/90, Olestra Anaerobic Biodegradation

EXHIBIT 14

Asymptotic CO_2, Rate Constants and Half-Lives for Olestra in Sludge Amended Soil*

Material	Initial Conc. (ppm)	Asymptotic % CO_2[1]	First-Order Rate Constant (1/Day)	Half-Lives[2] (Days)
Liquid Olestra	7.5	45.9 ± 1.4	0.09 ± 0.004	7.7
	75	53.9 ± 4.7	0.4 ± 0.01	17.3
	750	58.2 ± 2.9	0.07 + 0.003	9.9
		Liquid Olestra Avg.	**0.067**	**10.3**
Sucrose	1.09	50.1 ± 2.1	0.18 ± 0.69	3.9
	10.9	50.3 ± 2.3	0.24 ± 0.05	2.9
	10.9	54.5 ± 3.7	0.39 ± 0.11	1.8
Stearic Acid	0.86	67.7 ± 2.9	0.16 ± 0.01	4.3
	8.6	69.2 ± 0.5	0.16 ± 0.01	4.3
	86	73.7 ± 0.7	0.16 ± 0.01	4.3
Solid Olestra (in Hexane)	7.5	49.3 ± 0.8	0.0088 ± 0.0004	78.8
	375	47.6 ± 0.6	0.0090 ± 0.0003	77.0
Solid Olestra	7.5	42.0 ± 1.6	0.0057 ± 0.0005	121.6
	375	32.8 ± 0.4	0.0078 + 0.0002	88.8
		Solid Olestra Avg.	**0.0078**	**88.8**
Sucrose	1.09	60.3 ± 1.5	0.0881 ± 0.0060	7.9
	1.09	64.7 ± 1.7	0.1032 ± 0.0220	6.7
Stearic Acid	0.86	75.0 ± 1.3	0.0932 ± 0.0119	7.4
	86.0	68.3 ± 0.6	0.0957 ± 0.0368	7.2

* FAP Volume 2, Test Report E1 and FAP Supplemental Submission, Volume 65, 12/20/90

[1] Estimates ± Asymptotic Standard Errors

[2] Half-lives = 0.693 ÷ biodegradation rate constant

EXHIBIT 15

Calculation of Olestra Accumulation in Sludge-Amended Soil Accounting for Biodegradation

First-Order Accumulation Model

$C = \{\exp [-0.693 (CRT/BHL]\} \times C_0$[1]

$C_{\text{liquid olestra}} = \{\exp [-0.693 (365 \text{ days})/10 \text{ days}]\} \times 656 \text{ mg/kg}$
$= 0.0 \text{ mg/kg}$

$C_{\text{solid olestra}} = \{\exp [-0.693 (365 \text{ days})/88 \text{ days}]\} \times 656 \text{ mg/kg}$
37.0 mg/kg

Where: C = Concentration after 1 CRT
C_0 = Initial Concentration
CRT = Chemical Residence Time (days)
BHL = Biological Half-Life (days)

Assumes: No mobility
CRT = 365 days
$C_0 = C_{soil} = 656$ mg/kg[2]
BHL for liquid = 10 days; BHL for solid = 88 days
Application rate = once per year

Results:

	Steady-State Concentration[3]	Maximum Concentration[4]
$\text{Olestra}_{\text{liquid}}$	**0 mg/kg**	**656 mg/kg**
$\text{Olestra}_{\text{solid}}$	**39.2 mg/kg**	**695 mg/kg**

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[1] Shimp et al., 1990.

[2] See Exhibit 10 for calculation of C_{soil}.

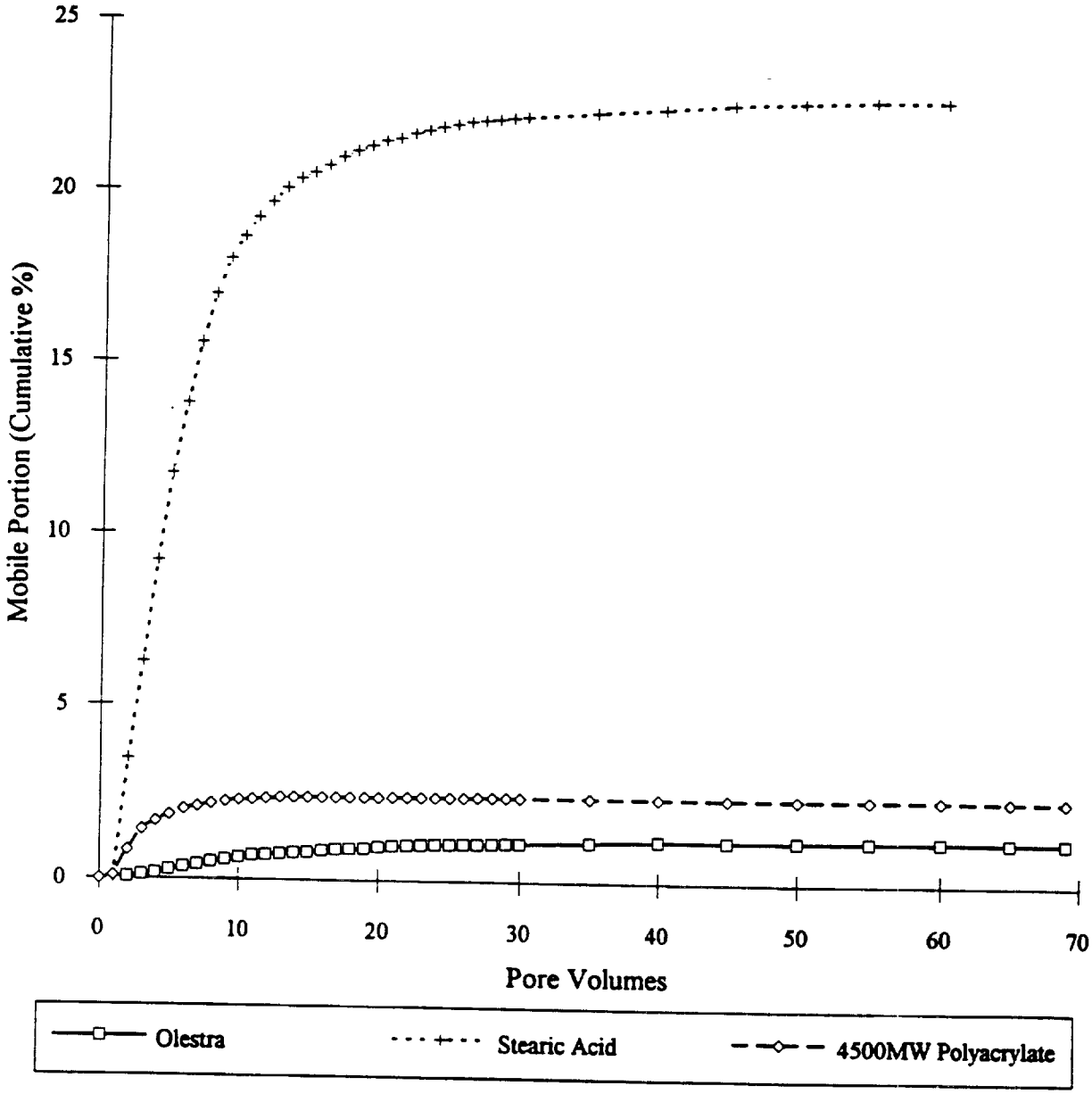
[3] Steady-State Concentration is determined by repetitive calculations of the first-order accumulation model until a constant value is achieved. This concentration is the predicted soil concentration after biodegradation has occurred at the end of any year prior to the new sludge application.

$C_t = (C_0 + C_{t-1}) \exp[-0.693(CRT/BHL)]$
where: the time step (t) is equal to the CRT

[4] Maximum concentration = concentration following new sludge application.

EXHIBIT 16

Mobility of Olestra in Borden Sand*



NOTE: One pore volume is approximately equal to one day.

* FAP Volume 2, Test Report E2

EXHIBIT 17

Calculation of Safe Level of Olestra in Sediments

1. A safe level of a chemical in sediments (r_{SQC}) is equal to the partitioning coefficient (K_p) times the water quality criteria determined from toxic levels observed in the standard aquatic species (c_{WQC}) These calculations are taken from OWRS, pages 3 through 5, 1989.

$$r_{SQC} = K_p c_{WQC}$$

2. K_p is the product of the organic matter divided by water partitioning coefficient (K_{oc}) and the fractional organic carbon content of the sediment (f_{oc}) (OWRS, pages 3 and 4, 1989):

$$K_p = f_{oc} K_{oc}$$

Because K_{oc} is seldom available, it is often approximated by the octanol/water partitioning coefficient (K_{ow}). For sediments, the relationship $K_{oc} = K_{ow}$ is often used. Thus, since the K_{ow} of olestra is 3500, the K_{oc} for olestra would be estimated as 3500.

3. An alternate approach to estimating K_{oc} was used by Gerstl (1990) who collected and analyzed sorption data for over 400 compounds. The group of compounds he studied which was most similar to olestra were the non-halogenated aromatic hydrocarbons. For this group, the relationship between K_{ow} and K_{oc} is provided below. The R^2 for the regression was 0.664.

$$\text{Log } K_{oc} = 0.529 \log K_{ow} + 0.919$$

Applying this to olestra:

$$\text{Log } K_{oc} = [(0.529)(3.55)] + 0.919 = 2.80$$

$$K_{oc} = 631.$$

4. Since aquatic testing of olestra did not show adverse effects or toxicity at the highest level tested, 1,000 mg/L, we use c_{WQC} = 1,000 mg/L.

5. To estimate $F_{oc,}$, we can make the a worst-case assumption that all of the stream bed is covered with a substantial depth of wastewater solids and then apply Sommers' (1977) organic carbon data, ~30%.

6. To solve for the safe level in sediments, r_{SQC}:

$$r_{SQC} = K_p c_{WQC} = f_{oc} K_{oc} c_{WQC}$$

   a. Using $K_{oc} = K_{ow}$ from (2) above:

   r_{SQC} = 3500 * 0.30 * 1000 ppm = 1,050,000 ppm or 105% of total sediment

   b. Using the more conservative Gerstl calculation in (3) above:

   r_{SQC} = 631 * 0.30 * 1000 ppm = 189,300 ppm or 19% of total sediment

EXHIBIT 18

Subacute Toxicity of Liquid Olestra to Earthworms
(Lumbricus terrestris)*

	Test Concentrations (mg/kg soil)					
	0	312.5	625	1250	2500	5000
% Mortality (cumulative)	2.5	5.0	2.5	0	2.5	7.5
% Abnormalities[1]	0	0	0	0	0	0
% Burrowing[2]	100	89	100	98	100	100
Average Weight Gain (g)	0.7 ± 0.2	0.8 ± 0.1	0.9 ± 0.1	0.9 ± 0.1	1.2 ± 0.1[s]	1.3 ± 0.3[s]

[1]Percent abnormalities on day 28.
[2]Percent of earthworms burrowing within 30 minutes, day 21.
[s]Statistically significant.

* FAP Supplemental submission, Volume 69, Terrestrial Toxicity Study with Olestra in Earthworms.

EXHIBIT 19

Subacute Toxicity of Solid Olestra to Earthworms
(Lumbricus terrestris)*

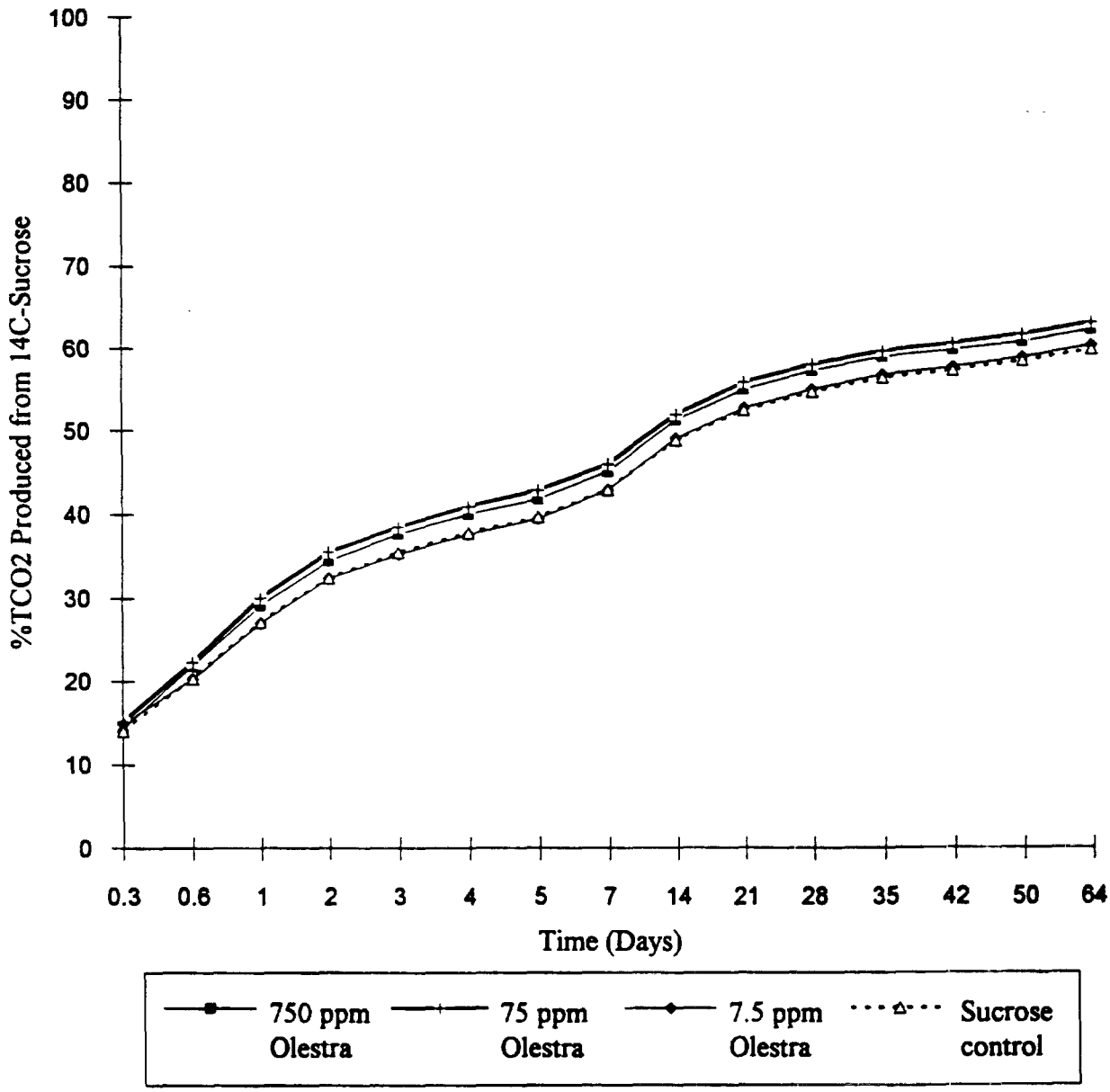
	Test Concentrations (mg/kg soil)					
	0	312.5	625	1250	2500	5000
% Mortality, cumulative	10	7.5	7.5	10	17.5	12.5
% Abnormalities[1]	2.5	2.5	2.5	0	0	2.5
% Burrowing[2]	100	94	100	100	100	100
Average Weight Gain (g)	0.3 ± 0.3	-0.1 ± 0.3	0.1 ± 0.2	0.0 ± 0.4	0.2 ± 0.3	0.3 ± 0.2

[1]Percent abnormalities on day 28.
[2]Percent of earthworms burrowing within 30 minutes, day 21.

* FAP Supplemental submission, Volume 54, 11/29/90, A Study Assessing the Potential Toxicity of Olestra to Earthworms.

EXHIBIT 20

Effects of Olestra on Sucrose Biodegradation by Sludge-Amended Soil Microbial Communities*



* FAP Volume 2, Test Report G1/E1

EXHIBIT 21

Seedling Growth Tests*

Lowest observed effect concentrations (LOEC) and no observed effect concentrations (NOEC) for the six plant species exposed to solid olestra, in mg/kg		
Species	LOEC	NOEC
Corn	> 930	930
Cucumber	> 930	930
Pinto Bean	430	220[a]
Ryegrass	> 930	930
Soybean	> 930	930
Wheat	> 930	930
[a]Based upon root weight, the most sensitive measured parameter for pinto bean, which was significantly reduced ($P \leq 0.05$) as compared to the control at the four highest concentrations tested according to Dunnett's Test.		

Lowest observed effect concentrations (LOEC) and no observed effect concentrations (NOEC) for the six plant species exposed to triglyceride shortening, in mg/kg		
Species	LOEC	NOEC[a]
Corn	> 960	960
Cucumber	190	< 190
Pinto Bean	830	580
Ryegrass	580	380
Soybean	610	350
Wheat	960	830
[a]Measurements of plant growth and weight (i.e., final shoot length, shoot weight, and root weight) and mortality are the endpoints used to determine the no observed effect concentration (NOEC).		

* FAP supplemental submission, Volume 64, Terrestrial Toxicity Studies Olestra and Triglycerides: Determination of Effects on Seedling Growth of Six Plant Species.

EXHIBIT 22

Effects of Liquid Olestra and Soybean Oil, Relative to a Control System, on Primary Wastewater Treatment Processes*

1. Effects on dynamic settling:

	Suspended solids removal (mean % + S. D.)		
Test Material Conc. (mg/L)	Control (No Dose)	Olestra	Soybean Oil
1	58.7 ± 1.5	62.2 ± 2.5	75.9 ± 0.4
10	66.4 ± 2.4	62.0 ± 2.5	64.7 ± 4.1
100	77.3 ± 2.9	71.1 ± 2.5	72.0 ± 3.5
200	66.8 + 1.2	70.2 + 0.8	67.1 + 1.0
Grand Mean	**66.8 ± 7.1**	**66.4 ± 4.8**	**69.9 ± 5.1**

2. Effects on batch settling:

	Settleable Solids (%)	
Test Material Conc. (mg/L)	Olestra	Soybean Oil
Control (No Dose)	71	76
1	73	79
10	74	80
100	75	82
200	80	85

* FAP Volume 2, Test Report H1/A2

EXHIBIT 23

Effects of Liquid Olestra and Soybean Oil, Relative to a Control System, on Suspended Solids and COD Removal During Secondary (continuous activated sludge) Treatment*

1. Effects on suspended solids removal[1]

Test Material	Suspended solids removal (mean % + S. D.)		
Conc. (mg/L)	Control (no dose)[2]	Olestra	Soybean Oil
0	91.6 + 2.7	88.9 + 4.8	90.3 + 2.6
1	89.9 + 6.9	93.9 + 1.3	92.5 + 2.6
10	86.5 + 11.3	89.7 + 1.4	91.3 + 1.6
100	87.0 + 9.6	80.2 + 12.2	90.1 + 2.0
200	87.3 + 3.5	93.4 + 1.5[S]	89.7 + 4.9

2. Effects on COD removal[1]

Test Material	COD removal (mean % + S. D.)		
Conc. (mg/L)	Control (no dose)[2]	Olestra	Soybean Oil
0	49.5 + 4.3	46.5 + 8.2	47.8 + 5.7
1	54.4 + 8.4	45.6 + 2.8	39.5 + 6.8[S]
10	53.6 + 7.7	43.3 + 10.9	46.8 + 10.8
100	47.4 + 2.8	19.4 + 11.9[S]	14.5 + 14.4[S]
200	36.9 + 11.9	33.8 + 23.9	28.9 + 22.4

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* FAP Volume 2, Test Report H2/B2

[1]Removals during 1 week prior to beginning of test.

[2]Five removal rates represent time series while olestra and soybean oil doses were increased.

[S]Difference between test chemical and control removals was statistically significant at $P < 0.05$.

EXHIBIT 24

Effects of Liquid Olestra on Anaerobic Digestion as Assessed by Reduction in Cumulative Gas Production (ml)*

	Olestra Concentration (mg/L)								
	0	1	10	100	250	1000	1500	5000	10000
Liquid Olestra 1	1051 + 23	1085	1115	1105		948			
Liquid Olestra 2	659 + 73			872		896		2826	---[a]
Liquid Triglyceride	659 + 73			1086		1352		3794	1063
Phenol	659 + 73				967		160[1]		
Solid Olestra	739 + 26			752		688		637	902
Solid Triglyceride	739 + 26			700		1143		5530	643
Phenol	739 + 26				649		205[b]		

* FAP Volume 2, Test Report H3 (liquid olestra 1) and FAP Supplemental Submission, Volume 68, Batch Anaerobic Digestion Inhibition Test (ADIT) of Olestra and Triglycerides.

[a] Statistical comparison at 10000 mg/L versus the control was not computed because the model used did not allow convergence.

[b] Significantly lower gas production at 5% risk level

EXHIBIT 25

Calculation of Olestra Accumulation in Septic Tank Tile Field Soil Accounting for Biodegradation

First-Order Accumulation Model

$C = \{\exp[-0.693(CRT)/BHL]\} \times C_0$[1]

Where:
- C = Soil Concentration after 1 CRT (mg/kg)
- C_0 = Initial Soil Concentration (mg/kg)
- CRT = Chemical Residence Time (days)
- BHL = Biological Half-Life (days)

Assumes:
- No Mobility
- CRT = 1 day
- BHL for liquid = 10 days; solid = 88 days
- C_0 = 2.2 mg/kg

Where: $C_0 = [(LR)(STE)]/[(SD)(BD)]$

Assumes:
- hydraulic loading rate of tile field (LR) = 2 gal. per day/ft^2
- septic tank effluent concentration of olestra (STE) = 4.8 mg/L
- soil penetration depth (SD) = 15 cm
- soil bulk density (BD) = 1.2 g/cm^3

Results:

	Steady-State Concentration[2]
$Olestra_{liquid}$	**30.6 mg/kg**
$Olestra_{solid}$	**278 mg/kg**

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[1]Shimp et al., 1990.

[2] Steady-State Concentration is determined by repetitive calculations of the first-order accumulation model until a constant value is achieved. This concentration is the predicted septic tank tile field soil concentration after biodegradation has occurred.

$C_t = (C_0 + C_{t-1}) \exp[-0.693(CRT/BHL)]$

where: the time step (t) is equal to the CRT

EXHIBIT 26

Procter & Gamble's Environmental Policy Statement

Procter & Gamble is committed to providing products of superior quality and value that best fill the needs of the world's consumers. As a part of this, Procter & Gamble continually strives to improve the environmental qualities of its products, packaging and operations around the world. To carry out this commitment, it is Procter & Gamble's policy to:

- **Ensure our products and operations are safe for our employees, consumers and the environment.**

- **Reduce or prevent the environmental impact of our products and packaging in their design, manufacture, distribution, use and disposal whenever possible.** We take a leading role in developing innovative, practical solutions to environmental issues related to our products, packaging and processes. We support the sustainable use of resources and actively encourage reuse, recycling and composting. We share experiences and expertise and offer assistance to others who may contribute to progress in achieving environmental goals.

- **Meet of exceed the requirements of all environmental laws and regulations.** We use environmentally sound practices, even in the absence of governmental standards. We cooperate with governments in analyzing environmental issues and developing cost-effective, scientifically-based solutions and standards.

- **Continually assess our environmental technology and programs and monitor progress toward environmental goals.** We develop and use state-of-the-art science and product life cycle assessment, from raw materials through disposal, to assess environmental quality.

- **Provide our consumers, customers, employees, communities, public interest groups and others with relevant and appropriate factual information about the environmental quality of P&G products, packaging and operations.** We seek to establish and nurture open, honest and timely communications and strive to be responsive to concerns.

- **Ensure every employee understands and is responsible and accountable for incorporating environmental quality considerations, in daily business activities.** We encourage, recognize and reward individual and team leadership efforts to improve environmental quality. We also encourage employees to reflect their commitment to environmental quality outside of work.

- **Have operating policies, programs and resources in place to implement our environmental quality policy.**

APPENDIX 1

This appendix contains a listing of the 220 snack and 120 cracker plants in the U.S., including location, number of employees, and size of metropolitan area. The locations and number of employees in this appendix are taken from Food Engineering's Directory of U.S. Food and Beverage Plants, Food Engineering, Chilton Company, Radnor, Pennsylvania, Sept. 1991. The size of the metropolitan area is taken from Rand McNally's 1993 Road Atlas which provides city sizes based on the 1990 census or latest available estimates.

DISTRIBUTION OF SNACK AND CRACKER PLANTS

BY SIZE OF PLANT VERSUS SIZE OF METROPOLITAN AREA

	Metropolitan Area Size			
Employees	< 25,000	25,000 - 100,000	100,000 - 500,000	500,000 +
< 100	Snacks: 59 Crackers: 33	Snacks: 34 Crackers: 17	Snacks: 48 Crackers: 18	Snacks: 15 Crackers: 14
100 - 499	Snacks: 12 Crackers: 5	Snacks: 7 Crackers: 4	Snacks: 11 Crackers: 3	Snacks: 1 Crackers: 1
500 - 999	Snacks: 3 Crackers: 3	Snacks: 5 Crackers: 3	Snacks: 6 Crackers: 7	Snacks: 2 Crackers: 2
1,000 - 2,499	Snacks: 1 Crackers: 0	Snacks: 1* Crackers: 0	Snacks: 1 Crackers: 3	Snacks: 2 Crackers: 0
2,500 +	Snacks: 0 Crackers: 0	Snacks: 1 Crackers: 0	Snacks: 0 Crackers: 0	Snacks: 0 Crackers: 1

* Procter & Gamble's Jackson, TN plant

APPENDIX 2
Summary of Test Reports

A.	Primary wastewater treatment	
	1. As part of a human feces mixture	FAP, Vol. 2, Report A1, 4/1/87
	2. Pre-contacted with domestic wastewater	FAP, Vol. 2, Report A2, 4/1/87
	3. Removal and Effects of olestra	FAP, Vol. 70, 3/1/91
	4. Adsorption to domestic sewage solids	FAP, Vol. 2, Report A3, 4/1/87
B.	Secondary wastewater treatment	
	1. Semi-continuous activated sludge	FAP, Vol. 2, Report B1, 4/1/87
	2. Continuous activated sludge	FAP, Vol. 2, Report B2, 4/1/87
C.	Fish bioconcentration	
	1. Octanol:water partition coefficient	FAP, Vol. 2, Report C1, 4/1/87
	2. Bioconcentration in Bluegill fish	FAP, Vol. 2, Report C2, 4/1/87
D.	Aquatic biodegradation	
	1. CO_2 production test	FAP, Vol. 2, Report D1, 4/1/87
	2. Biodegradation in activated sludge	FAP, Vol. 2, Report D2, 4/1/87
E.	Terrestrial fate	
	1. Biodegradation in soil - liquid olestra	FAP, Vol. 2, Report E1, 4/1/87
	2. Soil mobility	FAP, Vol. 2, Report E2, 4/1/87
	3. Biodegradation in soil-solid olestra	FAP, Vol. 65, 12/20/90
F.	Aquatic effects	
	1. Microbial toxicity	FAP, Vol. 2, Report F1, 4/1/87
	2. Algal toxicity (2 reports)	FAP, Vol. 2, Report F2, 4/1/87
	3. Daphnia toxicity	FAP, Vol. 2, Report F3, 4/1/87
	4. Fish toxicity	FAP, Vol. 2, Report F4, 4/1/87
G.	Terrestrial effects	
	1. Soil microbial inhibition	FAP, Vol. 2, Report E1, 4/1/87
	2. Seedling growth	FAP, Vol. 64, 10/24/90
	3. Earthworm toxicity - liquid olestra	FAP, Vol. 69, 3/15/91
	4. Earthworm toxicity - solid olestra	FAP, Vol. 54, 11/29/90
H.	Wastewater treatment effects	
	1. Effects on primary wastewater treatment	FAP, Vol. 2, Report A2, 4/1/87
	2. Effects on secondary wastewater treatment	FAP, Vol. 2, Report B2, 4/1/87
	3. Effects on anaerobic digestion - liquid olestra	FAP, Vol. 2, Report H3, 4/1/87
	4. Effects on anaerobic digestion - solid olestra	FAP, Vol. 68, 3/1/91

Statement of Compliance

All applicable studies were conducted in compliance with good laboratory practices effective at the time the studies were run. Those studies conducted before the effective date of the good laboratory practices regulations were reviewed and found to be in essential compliance with them.

APPENDIX 3

Summary of Key Environmental Risk Assessment Data for Olestra
(Data are for a projected olestra usage of 502 million lb/year)

A. Projected environmental concentrations:
   1. Influent municipal wastewater = 4.93 mg/L
   2. Effluent municipal wastewater = 0.7 - 1.4 mg/L
   3. Receiving streams = 0.20 - 0.42 mg/L
   4. Digested municipal sludge = 32.0 g/kg or 1281 mg/L
   5. Sludge-amended agricultural soils immediately following application = 656 mg/kg

B. Municipal wastewater treatment:
   1. Primary removal = 23 - 65%
   2. Secondary removal = 84% (CAS)

C. Environmental fate:
   1. Aquatic
      a. Bioconcentration in fish = none detected, bioaccumulation factor < 50 based on detection limit
      b. Biodegradation = 30 - 40% conversion to CO_2 after 49 days (initial conc. = 0.05 - 0.5 mg/L)
   2. Terrestrial
      a. Biodegradation:
         $Olestra_{liquid}$ = 50% conversion to CO_2 after 66 days (initial concentration = up to 750 ppm liquid olestra); average half-life = 10 days
         $Olestra_{solid}$ = 45% conversion to CO_2 after 386 days (initial concentration = up to 375 ppm solid olestra); average half-life = 88 days
      b. Mobility in soil = less than 1.2% after 70 pore volumes throughput

D. Environmental Effects:
   1. Aquatic = Acute LC_{50} > 1000 mg/L for bacteria, algae, zoo plankton and fish (highest concentration tested)
   2. Terrestrial = No significant effects on soil microbial activity, earthworms and crop plants in sludge-amended soil at levels exceeding maximum predicted exposures
   3. Wastewater treatment (POTW and on-site)
      a. Primary treatment = no effect up to 200 mg/L (highest concentration tested)
      b. Secondary treatment = no effect up to 200 mg/L (highest concentration tested)
      c. Sludge dewatering = no effect up to 200 mg/L (highest concentration tested)
      d. Anaerobic digestion = no effect on gas production at 10,000 mg/L

Petition Control Branch
Procter & Gamble Co.
25 February 1999

ATTACHMENT B

APPENDIX 1 - REVISED

This appendix contains a listing of the 220 snack and 120 cracker plants in the U.S., including location, number of employees, and size of metropolitan area. The locations and number of employees in this appendix are taken from Food Engineering's Directory of U.S. Food and Beverage Plants, Food Engineering, Chilton Company, Radnor, Pennsylvania, Sept. 1991. The size of the metropolitan area is taken from Rand McNally's 1993 Road Atlas which provides city sizes based on the 1990 census or latest available estimates. Available data on pre-packaged ready-to-heat popcorn plants were obtained from selected manufacturers.

DISTRIBUTION OF SNACK, CRACKER, AND PRE-PACKAGED READY-TO-HEAT POPCORN PLANTS BY SIZE OF PLANT VERSUS SIZE OF METROPOLITAN AREA

	Metropolitan Area Size			
Employees	< 25,000	25,000 - 100,000	100,000 - 500,000	500,000 +
< 100	Snacks: 59 Crackers: 33 **Popcorn: 2**	Snacks: 34 Crackers: 17	Snacks: 48 Crackers: 18	Snacks: 15 Crackers: 14
100 - 499	Snacks: 12 Crackers: 5 **Popcorn: 3**	Snacks: 7 Crackers: 4 **Popcorn: 1**	Snacks: 11 Crackers: 3 **Popcorn: 1**	Snacks: 1 Crackers: 1 **Popcorn: 1**
500 - 999	Snacks: 3 Crackers: 3	Snacks: 5 Crackers: 3	Snacks: 6 Crackers: 7	Snacks: 2 Crackers: 2
1,000 - 2,499	Snacks: 1 Crackers: 0	Snacks: 1* Crackers: 0	Snacks: 1 Crackers: 3	Snacks: 2 Crackers: 0
2,500 +	Snacks: 0 Crackers: 0	Snacks: 1 Crackers: 0	Snacks: 0 Crackers: 0	Snacks: 0 Crackers: 1

* Procter & Gamble's Jackson, TN plant

Petition Control Branch
Procter & Gamble Co.
25 February 1999

ATTACHMENT C

EXHIBIT 10 - REVISED

INITIAL CONCENTRATION OF OLESTRA IN SLUDGE-AMENDED SOIL
(for typical consumer consumption)

C_{soil} = C_{ds} x Incorporation Factor

C_{soil} = 32.0 g/kg x 0.0056 x 1000 mg/kg

= **179 mg/kg (ppm)**

Where:

C_{ds} = concentration in digested sludge

Incorporation factor = $\frac{\text{Annual Application Rate}}{\text{Incorporation Depth x Soil Bulk Density}}$

Assumes:

- Maximum usage levels of olestra (502 million pounds per year)
- Application rate = 1.0 kg sludge/m^2/year [1]
- Incorporation depth = 15 cm = 0.15 m [1]
- Soil bulk density = 1200 kg/m^3 [1]

Calculation of the Jackson plant contribution to the concentration of olestra in sludge amended soil:

$C_{(j)soil}$ = 15.6 g/kg x 0.0056 x 1000 mg/kg

= **87 mg/kg (ppm)**

Total initial concentration of olestra in soil amended with sludge from the Jackson POTW (i.e., input from consumer consumption and production plant):

C_{soil} + $C_{(j)soil}$ = 179 mg/kg + 87 mg/kg = 266 mg/kg

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[1] Federal Register Vol. 58, No. 32, p 9296, February 19, 1993.

Petition Control Branch
Procter & Gamble Co.
25 February 1999

ATTACHMENT D

EXHIBIT 15 - REVISED

CALCULATION OF OLESTRA ACCUMULATION IN SLUDGE-AMENDED SOIL ACCOUNTING FOR BIODEGRADATION

First-Order Accumulation Model

$C = \{\exp [-0.693 (CRT)/BHL]\} \times C_0$[1]

$C_{liquid\ olestra}$ = {exp [-0.693 (365 days)/10 days]} x 179 mg/kg
= 0.0 mg/kg

$C_{solid\ olestra}$ = {exp [-0.693 (365 days)/88 days]} x 179 mg/kg
10.1 mg/kg

Where: C = Concentration after 1 CRT
C_0 = Initial Concentration
CRT = Chemical Residence Time (days)
BHL = Biological Half-Life (days)

Assumes: No mobility
CRT = 365 days
$C_0 = C_{soil}$ = 179 mg/kg[2]
BHL for liquid = 10 days; BHL for solid = 88 days
Application rate = once per year

Results:

	Steady-State Concentration[3]	Maximum Concentration[4]
$Olestra_{liquid}$	**0 mg/kg**	**179 mg/kg**
$Olestra_{solid}$	**10 mg/kg**	**189 mg/kg**

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[1] Shimp et al., 1990.

[2] See Exhibit 10 for calculation of C_{soil}.

[3] Steady-State Concentration is determined by repetitive calculations of the first-order accumulation model until a constant value is achieved. This concentration is the predicted soil concentration after biodegradation has occurred at the end of any year prior to the new sludge application.

$C_t = (C_0 + C_{t-1}) \exp[-0.693(CRT/BHL)]$

where: the time step (t) is equal to the CRT

[4] Maximum concentration = concentration following new sludge application.